PUBLIC HEARING

BAR CODING - A REGULATORY INITIATIVE

July 26, 2002
9:00 a.m.

William H. Natcher Conference Center
Building 45
National Institutes of Health
45 Center Drive
Bethesda, Maryland

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                        P A N E L I S T S

FDA Panel (a.m.)

Margaret M. Dotzel, Esq., Moderator
Lester Crawford, D.V.M.
Theresa Mullin, Ph.D., Associate Commissioner,
    Planning and Evaluation, FDA
Steven Galson, M.D., M.P.H., Deputy Director,
    Center for Drug Evaluation and Research, FDA
Diane Maloney, Associate Director for Policy,
    Center for Biologics, FDA
David Feigal, J.D., Director, Center for
    Devices and Radiological Health, FDA
Erica L. Keys, Esq., Office of Chief Counsel,
    HHS

FDA Panel (p.m.)

Margaret M. Dotzel, Esq., Moderator
Steven Galson, M.D., M.P.H.
Diane Maloney, Associate Director for Policy, Center
    forBiologics Evaluation and Research, FDA
David Feigal, M.D.
Peter C. Beckerman, Esq., Office of Chief
    Counsel, HHS
Nancy C. Gieser, Ph.D., Office of Planning
    and Evaluation, FDA

A G E N D A

1   P R O C E E D I N G S

2   MS. DOTZEL: My name is Peggy Dotzel, and I'm

3   the Associate Commissioner for Policy at the FDA. And

4   I will be your moderator today. On behalf of the FDA,

5   I'd like to welcome everyone here. And to get started,

6   what I'd like to do is introduce you to the FDA panel.

7   Actually, first what I'd like to do -- I

8   apologize -- is to thank Chuck Daniels -- he's the

9   director of pharmacy services at the Nih Pharmacy

10   Department -- for cosponsoring this meeting today.

11   And now I'd like to acquaint you with the FDA

12   panel.

13   First we have our deputy commissioner,

14   Dr. Lester Crawford. From our Center for Drugs, we

15   have Dr. Steven Galson, who's the deputy director.

16   From our Center for Devices, we have the center

17   director, Dr. David Feigal.

18   Joining me from the Commissioner's office,

19   we have Dr. Theresa Mullin, who is our associate

20   commissioner for planning. From the Center for

21   Biologics, we have Diane Maloney, who is the associate

22   director for policy. And from our Office of Chief

1 Counsel, we have Erica Keys.

2   And now I'd like to turn the floor over to

3 Dr. Crawford.

4   DR. CRAWFORD: Thank you very much, Peggy.

5 It's a pleasure to be here, and it's a great thrill to

6 see so many people come out on a stormy morning. And I

7 hope that the storms are now over, both outside and

8 inside.

9   It's my pleasure to talk about this morning

10 how best to develop a regulation on barcode labeling

11 for human drugs and biological products, and what

12 should be the scope of such a rule. We will also begin

13 to explore the feasibility of barcoding medical

14 devices.

15   The issue before us goes to the heart of FDA's

16 responsibility to the American people as the agency

17 charged with the promotion and protection of public

18 health. One of FDA's most exacting and critical duties

19 is to make sure that drugs and medical devices that are

20 used to treat patients are as safe as well as

21 effective, and that their benefits outweigh their

22 risks.

1   To meet this requirement, the pharmaceutical

2 and device industries spend millions of dollars on

3 conducting carefully designed and demanding clinical

4 trials. And our agency uses still more resources,

5 including state-of-the-art scientific expertise, to

6 submit the results of these trials to a rigorous

7 review.

8   The mutual goal is to make sure that each drug

9 and device that reaches our market is as safe as it is

10 humanly possible to make it. And we are confident that

11 the products we approve meet that high standard.

12   Healthcare products that receive FDA's

13 approval can be relied upon to develop important

14 medical benefits. But they must be properly used.

15 Unfortunately, that is not always the case.

16   Medication errors are a serious public health

17 hazard, whether they are caused by a wrong diagnosis,

18 misread prescription, mistaken dosage, incorrect device

19 use, or poorly followed medication regimen. These

20 errors can invalidate all of the expense, effort, and

21 scientific erudition that had been invested into making

22 these products safe and effective, with tragic

1 consequences for the patient.

2   Research cited by the National Academy of

3 Sciences three years ago estimated that up to 100,000

4 patients die from preventable medical errors in

5 hospitals alone. Medical errors are the eighth leading

6 cause of death in the United States, or, as Secretary

7 Thompson has put it, the equivalent of two passenger

8 planes crashing every three days.

9   We believe that 30 to 50 percent of these

10 deaths are associated with errors involving the use of

11 FDA-regulated medical products, drugs, vaccines, blood

12 and blood products, and medical devices.

13   In addition to the human cost, the economic

14 cost of these errors is staggering. According to some

15 studies, preventable morbidity and mortality related to

16 drugs alone increases the nation's healthcare bill by

17 more than $177 billion per year. Reducing this

18 enormous toll, which exceeds the annual traffic

19 fatalities on our highways, has been a high FDA

20 priority for more than 20 years.

21   Over the years, our agency has addressed the

22 hazard of medication errors by initiating many consumer

1   and health professional-oriented measures. These

2   include: medication guides; drug- and disease-specific

3   education programs; improved prescription and over-the-

4   counter label formats; risk management initiatives; and

5   a review of proposed product names to prevent their

6   mixup with drugs already on the market.

7   Today we will discuss the pros and cons of yet

8   another innovative measure that will help reduce

9   preventable drug-related injuries and deaths, and that

10 is the application of barcoding to human pharmaceutical

11 products, biological products, and medical devices.

12   This is an important initiative that could

13 bring great benefits to the public health because we

14 know that barcoding can help ensure that the right

15 patient gets the right drug and the right dose of it at

16 the right time.

17   The use of barcoding in several hospitals has

18 shown that the system can significantly diminish

19 medication errors. For example, we have invited a

20 representative of the Veterans Administration Hospital

21 in Chicago, Illinois to tell us about their experience

22 with the barcoding system that is estimated to have

1   prevented about 380,000 medication errors in a

2   five-year period. And we all look very much forward to

3   hearing that presentation.

4   One hospital in New Hampshire registered an

5   80 percent reduction in medication errors, and a

6   medical center in Colorado reduced its medication rate

7   [sic] by more than 70 percent. In both cases, as a

8   result of their use of barcoding, these accomplishments

9   were achieved. A 70 percent reduction in medication

10   error rate is probably about as good as it can get.

11   The healthcare industry has projected that the

12   use of barcoding across the medical supply chain could

13   result in substantial annual savings. So we are very

14   interested in your views, all of you here, on how a

15   barcoding regulation should work, what it may cost to

16   implement, and how it would affect patient safety.

17   Peggy Dotzel, FDA's associate commissioner for

18   policy to my right, will be the moderator of today's

19   discussions. In addition, we have other senior

20   managers from our office and from FDA's Centers for

21   Drugs, Biological Products, and Medical Devices. And

22   we are all eager to hear your thoughts and suggestions

1   on this matter.

2   Once again, I want to thank you for attending

3   this important meeting, and I hope you will find

4   today's discussions useful and stimulating. And now

5   I'll turn the proceedings back over to Ms. Dotzel.

6   Thank you very much.

7   MS. DOTZEL: Thank you, Dr. Crawford.

8   Before we continue on with the agenda, I'd

9   like to go over a few housekeeping details. First of

10   all, we have noticed that a number of you have luggage

11   with you, and if you'd like, they can store that

12   luggage for you out at the registration desk so you

13   don't have to keep it at your seats here.

14   Also, submissions to the docket can be made

15   out at the registration desk. And the closing date for

16   submissions to the docket is August 9th.

17   And then lastly, a transcript of today's

18   meeting will be available, hopefully in about two

19   weeks. And it will be available on our website.

20   You hopefully have also received out at the

21   registration desk a copy of our agenda for today. As

22   you can see from the agenda, we have a very full day.

1 We have some -- we have two panels scheduled to

2 present, and then we have over 35 additional people who

3 have registered to speak.

4   Because we have so many interested parties and

5 because we have so much to accomplish, I am really

6 going to ask the speakers to stick to the allotted

7 time. We have a timer set up here so that you will see

8 what -- you know, how your time is going. A yellow

9 light will come on when there is a minute left. And

10 then a red light will flash when your time is up.

11   And I apologize in advance if I have to start

12 cutting people off, but like I said, we really have a

13 lot to get through and I'd like to give everyone who

14 has registered an opportunity to say their piece, and

15 also I'd like for everyone to be able to go home for

16 the weekend. So again, I really urge people to keep

17 their eye on the clock so that we can keep things

18 moving.

19   With that, I'd like to move on to our first

20 agenda item. As Dr. Crawford noted, the VA hospital

21 already has had experience with using a barcoding

22 system. We have with us here today Kay Willis, who is

1   the chief of pharmacy at the VA Medical Center in

2   Chicago, and she is going to present a video that

3   provides an overview of the system that they are using

4   in their hospital.

5   We are having some technical difficulties with

6   the video and the sound is not very high, so I am

7   really going to ask people to try to keep the

8   background noise down while this video is being

9   presented.

10   And with that, Kay?

11   MS. WILLIS: Okay. This is a tape from the

12   Pinnacle Awards from the American Pharmaceutical

13   Association. And it has been edited due to time

14   constraints. So you can roll the tape.

15   (A videotape was played.)

16   MS. WILLIS: The medical literature clearly

17   shows that medication errors have the potential to

18   compromise patient safety and dramatically increase

19   healthcare costs. The sources of medication errors are

20   multi-disciplinary and often system-related. Within

21   the Department of Veterans Affairs, a barcode

22   medication administration system, or BCMA, has been

1   developed and implemented that addresses these issues.

2   The Department of Veterans Affairs is

3   committed to improving patient safety through the use

4   of barcodes and technology. VA pioneered the use of

5   barcodes to improve the medication administration

6   process at the VA Medical Center in Topeka, Kansas

7   beginning in the early 1990s.

8   Data collected on reported medication errors

9   from 1993, the last year before the barcode system was

10   implemented in Topeka, compared to post-implementation

11   data reported for 2001, show that Topeka VA was able to

12   reduce its reported medication errors by an astounding

13   86.2 percent compared to the base year.

14   The medication error improvements by type of

15   event include: 75.5 percent improvement in errors

16   caused by the wrong medication being administered to a

17   patient; 93.5 percent improvement in errors caused by

18   the incorrect dose being administered to a patient;

19   87.4 percent improvement in wrong patient errors; and

20   70.3 percent improvement in errors caused when

21   medications scheduled for administration were not

22   given.

1   The Veterans Health Administration mandated

2   the use of BCMA in June 2000 at all 173 medical centers

3   in its network. Expansion of the BCMA software to

4   include validation of IV medications has been added in

5   Version 2. VHA has mandated that Version 2 be

6   implemented by November 30, 2002.

7   One of the things VA is currently struggling

8   with is a lack of barcodes on IV solution packaging.

9   The national IV contract is coming to an end soon, and

10 VHA will likely make barcoding a contract requirement

11 for the next solicitation.

12   The National Center for Patient Safety was

13 created as the patient safety arm of VHA. This office

14 has worked to further improve the BCMA program within

15 VA and facilitate the implementation of Version 2.

16   VHA pharmacy leadership is committed to

17 patient safety and has made great strides in its

18 endeavors. In addition to BCMA, VA's consolidated mail

19 outpatient pharmacies, or CMOPs, have a lower error

20 rate than other comparable facilities because of the

21 use of barcodes and technology.

22   The drug is checked by a pharmacist via

1   screens that print an image of the drug that can easily

2   be matched to the medication in the bottle. Drugs

3   loaded into the automated equipment are barcoded for

4   accuracy before they are loaded. Barcodes are also

5   used in inventory management for ordering, receipt, and

6   stocking within CMOPs.

7   VA's standardization of the appearance of

8   multi-source generic products across the system by

9   using committed use, multi-year contracts also promotes

10 patient safety by alleviating patient confusion over

11 differently appearing products.

12   VA recommends the implementation of uniform

13 barcode standards down to the immediate unit of use

14 package for legend drugs, over-the-counter drugs,

15 vaccines, blood derivatives, and IV solutions.

16   Currently, VA pharmacies are required to

17 repackage or relabel most unit of use products for

18 inpatient use. Nationally, 14 percent of all

19 preventable intercepted and non-intercepted adverse

20 drug events result from dispensing errors alone. The

21 incidence of dispensing errors increases with each

22 product that requires repackaging.

1   Manufacturers' barcodes on unit of use

2 products would eliminate the need for repackaging prior

3 to dispensing, thereby reducing or eliminating the

4 potential for error associated with repackaging.

5   Uniform barcode standards should include the

6 national drug code, lot number, and expiration date.

7 VA invites our industry partners to help in reducing

8 medication errors and improving patient safety by

9 embracing barcodes on all immediate unit of use

10 packaging.

11   Once standards are reached, the national

12 acquisition center can put some teeth into barcoding

13 requirements in its solicitations. It is time for the

14 pharmaceutical industry to continue its contribution to

15 improving healthcare in the U.S. by voluntarily

16 adopting uniform barcode standards and implementing the

17 technology into all commercially-available products as

18 soon as practical.

19   A medical student called me last week to

20 discuss a possible medication error at another

21 hospital. Two sound-alike medications were involved in

22 the error. The student asked, "Mom, this wouldn't have

1   happened if we had BCMA."

2   Thank you.

3   MS. DOTZEL: Thank you very much, Kay.

4   And now we're going to have our first panel

5   come up. The first panel this morning is a panel of

6   representatives from various health professional

7   organizations, and I'm going to ask them to come up to

8   the stage now.

9   Okay. The way we're going to do this this

10 morning is we're going to ask the different panel

11 members to come up to the podium and give your

12 presentations, and then after that we will have an

13 opportunity for the FDA panel to ask you some

14 questions. And if time permits, we will then also turn

15 to the audience, and if the audience has any questions,

16 we have mikes in each of the two aisles and you can

17 come up and ask your questions.

18   First, from the American Hospital Association,

19 we have John -- is John not here? All right.

20   Well, we will move on to Kasey Thompson, who

21 is here from the American Society of Health System

22 Pharmacists.

1   MR. THOMPSON: Good morning. My name is Kasey

2 Thompson, and I am the director of the Center on

3 Patient Safety of the American Society of Health System

4 Pharmacists.

5   ASHP is the 30,000-member professional

6 association that represents pharmacists who practice in

7 hospitals, health maintenance organizations, long-term

8 care facilities, home care agencies, and other

9 components of healthcare systems. I am pleased to

10 provide you with ASHP's views on the proposal to

11 require that pharmaceutical manufacturers include

12 barcoding on all drug products.

13   Before I address the question that the FDA

14 asked in its announcement of this meeting, I would like

15 to draw the FDA's attention to one point. Barcoding

16 technology is entrenched throughout America in all

17 types of venues -- grocery stores, department stores,

18 libraries. It is something that everyone expects, and

19 it is found everywhere except where it can do the

20 greatest good, saving lives.

21   This is a high urgency public health and

22 safety issue, and the time for action is now. ASHP has

1   long supported the use of barcoding technology to help

2   prevent patient harm resulting from medication errors.

3   ASHP adopted a policy in 2001 to urge the Food and Drug

4   Administration to mandate that standardized machine-

5   readable coding be placed on all manufacturers'

6   single-unit drug packaging to, one, ensure the accuracy

7   of medication administration; two, improve efficiencies

8   within the medication use process; and three, improve

9   overall public health and patient safety.

10   This is not a new concept. We know that the

11   FDA has heard this recommendation numerous times.

12   Finally, last December, the FDA announced in its

13   semi-annual agenda that it would publish a proposed a

14   rule requiring barcoding on drug and biological

15   products. ASHP welcomed the FDA's announcement, and

16   supports its stated purpose of reducing medication

17   errors.

18   But again, time is slipping by. The most

19   recent agency guess is that the proposed rule would be

20   issued in November. ASHP has criticized the FDA in the

21   past for dragging its feet on necessary changes in drug

22   product packaging to ensure patient safety. The need

1   for this step is great, and the time for it is long

2   overdue.

3   ASHP has the following specific comments

4   related to the questions the FDA asked in the Federal

5   Register notice announcing this July 26th public

6   hearing.

7   Number one, which medical products should

8   carry a barcode? What about blood products and

9   vaccines?

10   Barcodes should be required on all

11 pharmaceutical product packages down to the unit dose,

12 single unit level. For barcoding to be effective in

13 hospitals and health systems, products in unit dose

14 packages must be made available by pharmaceutical

15 manufacturers.

16   While we have received reports that some major

17 manufacturers are about to make a public commitment to

18 add barcodes to all packaging, including unit dose,

19 some of our members report a disturbing trend whereby

20 fewer and fewer manufacturers are producing drug

21 products in unit dose packages, leaving repackaging up

22 to individual hospitals.

1   This is a major concern. Not only does

2 repackaging introduce new opportunities for mistakes to

3 be made, it adds an additional cost which most average-

4 to small-sized hospitals cannot afford. Repackaging

5 also takes pharmacists away from their most important

6 duty in hospitals, that is, managing patients' drug

7 therapy.

8   There is evidence from over 40 years of

9 research that proves that unit dose drug distribution

10 systems improve patient safety by reducing medication

11 errors, improving efficiency, and reducing costs.

12   The second question: What information should

13 be contained in the barcode that is critical to

14 reducing medical product errors?

15   Barcodes on drug products must contain the

16 product's NDC number. This is the primary element that

17 will be effective in meeting the expectation that

18 health professionals will be able to verify that the

19 patient is receiving the right drug at the right dose

20 and at the right time.

21   Other elements that should be mandated include

22 the product's lot number, which can identify products

1   for the purposes of drug recall; a database can link a

2   specific lot to a drug given to a specific patient.

3   Inclusion of the lot number would also be useful during

4   public health crises where mass vaccinations or drug

5   treatments need to be given.

6   The third data element, product's expiration

7   date. Drugs are kept in numerous places throughout

8   hospitals, and even with the diligent efforts of

9   pharmacists and technicians to check for out-of-date

10 drug products, it is impossible to verify and find all

11 of them. Placing the expiration date on the barcode

12 would tell the nurse at the patient's bedside if a drug

13 is out of date before the patient gets the drug.

14   Third question: Should the proposed

15 regulation adopt a specific barcode symbology?

16   Numerous symbologies exist for machine-

17 readable coding of products, but some are receiving

18 more attention than others because of their ability to

19 fit on small package sizes and readability by most

20 commercially-available scanners.

21   Common information systems standards need to

22 be developed, either by FDA mandate in the proposed

1 regulations or through collaboration between industry,

2 healthcare professionals, and technology experts, and

3 consistently applied, for barcode systems to

4 effectively interface with other hospital computer

5 systems such as pharmacy, laboratory, blood bank, and

6 billing systems, just to name a few.

7   Fourth question: Where on the package of drug

8 products should the barcodes be placed?

9   The barcodes should appear on both the inner

10 and outer wrap below the human-readable information.

11 Barcodes on outer wraps are useful for inventory and

12 distribution control. Barcodes on inner packaging are

13 imperative at the time of drug administration.

14   Fifth question: What products already contain

15 barcodes? Who uses the barcodes and how?

16   Reliable data does not exist on how many

17 current products packaged in unit dose form contain

18 barcodes, but it is well recognized that that number is

19 few, especially for unit dose packages containing a

20 standard barcode and the necessary data elements of

21 lot, NDC, and expiration date.

22   The Department of Veterans Affairs, as we have

1 heard, is a national leader in using barcoding systems

2 for scanning patient, nurse, and drugs at the bedside.

3 A 1999 ASHP survey revealed that only 1.1 percent of

4 U.S. hospitals used barcoding to scan patient, nurse,

5 and drug at the bedside.

6   We are all aware, however, of mounting public

7 pressures to improve patient safety. Once drug product

8 packaging has barcodes, the pressure to improve patient

9 safety by applying barcoding technology in

10 institutional settings will escalate.

11   Institutions need incentives to use this

12 important patient safety-enhancing technology. This

13 can be achieved through an FDA requirement and

14 commitment by manufacturers to do what is right for

15 patients. Include barcodes on all product packages and

16 make all product packages available in unit dose.

17   Sixth question: What is the expected rate of

18 acceptance of machine-readable technologies in

19 healthcare sectors? What are the benefits of using

20 this technology in delivering healthcare services and

21 other potential uses?

22   Practitioner demand for barcodes on

1   prescribing -- on prescription drug products and the

2   capability of implementing such technology exists.

3   More hospitals and health systems are in various stages

4   of adopting machine-readable coding systems. What is

5   needed is the product packaging that would allow its

6   use.

7   The benefits of using machine-readable coding

8   in healthcare sectors are twofold. First and foremost,

9   a barcode system will improve patient safety by

10 ensuring that the right patient gets the right dose of

11 the right drug by the right route at the right time.

12   Second, a properly designed and implemented

13 barcode system will enhance the efficiency and work

14 flow of pharmacists, nurses, and other health

15 professionals using the technology. A barcode system

16 will be useful in bedside scanning, inventory control,

17 billing, and laboratory systems.

18   Seventh question: When should a final rule

19 requiring barcoding on drug products become effective?

20   We hope that there will be no more delays in

21 an FDA requirement and commitment by manufacturers to

22 do what's right for patients. Clearly, an early

1   effective date is necessary.

2   We're afraid, however, that from the continual

3   hesitation to take action on this issue, we will not

4   see anything from the FDA soon. If a proposed rule is

5   not issued until this fall, even with a short public

6   comment period it will probably be at least a year from

7   now until we see the Agency's final rule.

8   How much time, then, will be given to

9   manufacturers to make the necessary changes? A year or

10 two? Market demand by end users -- hospitals,

11 healthcare practitioners, wholesalers, and patients --

12 can help drive the speed at which drug manufacturers

13 implement the new regulation.

14 ASHP appreciates the opportunity to comment to

15 the FDA on this significant issue. We are ready to

16 assist the agency in any way in developing its proposed

17 and final regulations requiring barcoding on drug and

18 biological products. Thank you.

19 MS. DOTZEL: Thank you, Kasey.

20 I'd next like to invite Dr. Joseph Cranston,

21 who is here representing the American Medical

22 Association.

1   DR. CRANSTON: Good morning. My name is

2   Joseph Cranston. I'm a pharmacologist by training.

3   And I currently serve as the director of science,

4   research, and technology at the American Medical

5   Association.

6   The AMA is the largest national professional

7   association representing physicians and physicians in

8   training, and I am speaking on behalf of the AMA at

9   this meeting.

10   The AMA has had a longstanding commitment both

11   to improve the quality of medical care delivered to

12   patients by their physicians and to promote efforts

13   that will improve patient safety. For example, the AMA

14   established the National Patient Safety Foundation in

15   1997, and has participated in a number of initiatives

16   on clinical quality improvement. The AMA also has been

17   a partner and strong supporter of MedWatch, the FDA's

18   adverse incident reporting program.

19   In 1999, the Institute of Medicine published

20   its seminal report, "To Err Is Human," which raised

21   public awareness to the important issue of patient

22   safety. As discussed in that report, there is

1 considerable documentation in the medical literature

2 that medication errors result in numerous patient

3 injuries and deaths. This situation is unacceptable,

4 and efforts must be made to minimize medication errors.

5 Evidence suggests there are numerous causes of

6 medication errors, and therefore a variety of

7 approaches will be needed to address this problem. The

8 implementation of new information technologies is an

9 area that offers enormous opportunities to improve

10 patient safety. And the use of machine-readable

11 coding, that is, barcoding, is one such technology.

12 The incorporation of scannable barcodes in a

13 standardized format on all medication packages and

14 containers should help ensure that the right drug and

15 dose are administered to the correct patient. Thus,

16 the AMA supports and encourages efforts to create and

17 expeditiously implement a national barcoding system for

18 prescription and over-the-counter medicine packaging in

19 an effort to improve patient safety.

20 The extension of barcoding to other FDA-

21 regulated products, such as blood products, vaccines,

22 and certain medical devices, also appears to be a

1   reasonable and attainable goal.

2   The AMA has no official position on the

3   specific elements that should be included in a proposed

4   rule on barcoding. As a general comment, the AMA

5   encourages the FDA to balance the need to put uniform

6   barcode standards into place as soon as possible to

7   reduce medication errors with the need not to stifle

8   further innovation in barcode technology.

9   As a start, the AMA believes the June 2001

10   recommendations of the National Coordinating Council

11   for Medication Error Reporting and Prevention,

12   otherwise known as NCCMERP, entitled, "Preventing and

13   Standardizing Barcoding on Medication Packaging,

14   Reducing Errors, and Improving Care," should be given

15   strong consideration by the FDA.

16   The NCCMERP recommendations were developed by

17   a coalition of stakeholders, including representatives

18   from medicine, pharmacy, nursing, consumers, risk

19   managers, hospitals, accrediting bodies, the

20   pharmaceutical industry, and government agencies,

21   including the FDA.

22   In developing its recommendations, the council

1 conducted a thorough literature review and held a

2 conference of invited experts in August 2000 to discuss

3 needs assessment, current standards, equipment

4 manufacturers, and cost implications. While the

5 NCCMERP recommendations on barcodes focus on

6 institutional settings such as hospitals, the

7 recommendations may be applicable to other settings.

8 Now, the FDA is undoubtedly very familiar with

9 the NCCMERP recommendations. However, the AMA would

10 like to just briefly mention some of the key points for

11 the record.

12 First, the FDA, the United States

13 Pharmacopeia, the pharmaceutical industry, and other

14 appropriate stakeholders should establish and implement

15 uniform barcode standards, down to the immediate unit

16 of use packaging, as defined in the U.S. PNF.

17 Two, the barcode should contain three data

18 elements. A Uniform National Drug Code or NDC number

19 should be the primary unique product identifier.

20 Second, either the lot, control, or batch number should

21 be one secondary identifier, and the expiration date as

22 another secondary identifier.

1   Point number three, the three data elements --

2 the NDC, the lot number, and the expiration date --

3 should be uniformly ordered on the barcode using

4 existing symbologies.

5   Fourth, there should only be one barcode on

6 the label and it should have a standardized location.

7   And finally, the barcode should be included on

8 the immediate container, labels of all commercially

9 available prescription and OTC medications in any

10 dosage form, on intermediate containers or cartons, and

11 on shelf-keeping units.

12   As emphasized by NCCMERP, its recommendations

13 are "a first step to the ultimate use of barcodes in

14 the medication use process." Before hospitals,

15 physicians, pharmacists, nurses, and especially

16 patients can benefit optimally from this technology,

17 barcodes must be uniformly present in a standardized

18 format on unit of use packaging of all commercially

19 available prescription and over-the-counter drug

20 products.

21   In conclusion, the implementation of a

22 national system for barcoding of commercially available

1 drug products and possibly other FDA-regulated products

2 should help physicians and other health professionals

3 to decrease the number of medication errors and the

4 harm to patients that is associated with these errors.

5 The AMA urges the FDA to quickly move forward with a

6 proposed rule to require barcodes on drug product

7 packaging. Thank you.

8   MS. DOTZEL: Thank you, Dr. Cranston.

9   Next, from the National Alliance of Health

10 Information Technology, we have Tim Zoph.

11   MR. ZOPH: Thank you. Good morning. I am Tim

12 Zoph. I'm vice president and chief information officer

13 for Northwestern Memorial Hospital in Chicago,

14 Illinois.

15   I'm here today on behalf of the new National

16 Alliance for Health Information Technology, or known as

17 the Alliance, a group of approximately 50 organizations

18 representing providers, purchasers, manufacturers, and

19 standard-setting organizations committed to "mobilize

20 the field to address the fragmentation and lack of

21 coordination in healthcare, improving quality and

22 performance through standards-based information

1 systems."

2 We are pleased to have the opportunity to

3 testify on an issue of critical importance for the

4 healthcare industry and the people they serve, the

5 barcoding of drug labels for unit of use

6 pharmaceuticals.

7 Northwestern Memorial Hospital is a founding

8 member of the Alliance and is committed to the first

9 initiative of the Alliance, promoting the use of

10 barcoding technology to create a safer, more efficient

11 and effective patient care. I am here today to present

12 the consensus recommendations of the Alliance to the

13 FDA for their consideration as they develop a rule for

14 the barcode labeling of human drug products.

15 By way of background, healthcare has trailed

16 virtually every other industry in reaping the benefits

17 of information technology advances, at least in part

18 due to, one, a lack of consistent and uniform standards

19 and protocols; two, its dependence on multiple

20 scientific disciplines and medical specialities, each

21 with its attendant technical requirements and demands.

22 As a result, the healthcare environment is

1 extremely fragmented, with isolated systems and

2 databases. To improve the situation, the industry must

3 begin to approach this more strategically.

4 The Institute of Medicine report, "Crossing

5 the Quality Chasm," calls for "a national consensus on

6 comprehensive standards for the definition, collection,

7 coding, and exchange of clinical data." In comparison

8 to other industries, healthcare has been slow to

9 achieve this consensus. As a result, there has been an

10 apparent failure to leverage even their limited

11 investment in information technology aimed at improving

12 patient outcomes and operational efficiency.

13 There are multiple causes for this failure,

14 but one important cause is the absence of a

15 standardized barcode on the label of unit of use

16 pharmaceutical packaging. Only approximately

17 35 percent of all drugs administered at the bedside

18 contain a barcode, which when used in conjunction with

19 decision support tools, could dramatically reduce the

20 incidence of medication errors.

21 The Alliance recognizes that the

22 implementation of barcodes on unit of use medication

1 packaging is only the first vital step in realizing the

2 promise of barcode technology in making our healthcare

3 system safer. A set of recommendations for the

4 National Coordinating Council for Medical Error

5 Reporting and Prevention already exists and is a good

6 starting point for discussion of barcoded labeling

7 standards.

8   The Alliance reviewed these standards, and

9 building upon them offers the following recommendations

10 in response to the FDA's questions.

11   Firstly, for the proposed rule, the barcode

12 label requirement, the Alliance supports the FDA's

13 effort to propose a rule to require a barcode on the

14 label of human drug products down to the unit of use

15 packaging.

16   Our recommendations, based on the considerable

17 expertise of our member organizations, can help the FDA

18 to further define the details of a barcode

19 implementation process for human drug products.

20 Additionally, we desire to work with the FDA on further

21 implementation of barcoding in healthcare to promote

22 patient safety and protect patients from human and

1 system errors.

2 It is our desire today, in today's public

3 hearing, it will aid the healthcare field and the FDA

4 in achieving consensus on the prompt establishment of

5 regulations for barcode labeling on human drug products

6 down to the unit of use level.

7 Drugs and biologicals: The Alliance supports

8 the implementation of a requirement for barcoding for

9 all commercially available prescription and

10 nonprescription medications. The code must be included

11 on the labels of all unit of use pharmaceutical

12 packaging.

13 All dosage forms, including oral solids, oral

14 liquids, injectables, inhalers, nasal sprays, topicals,

15 and other forms of specialized drug product packaging

16 should include a barcode on their label. In addition

17 to unit of use packaging, intermediate containers and

18 cartons and shelf-keeping units should also be labeled

19 with a barcode.

20 Eventually, vaccines, blood, and blood

21 products should have an FDA requirement for labeling

22 with a standardized barcode. Currently, only blood has

1 a barcode, and even it is not mandatory. Barcodes for

2 vaccines are currently under investigation by the CDC.

3 The absence of barcodes in blood products and vaccines

4 could raise safety issues, especially for the tracking

5 of contaminated products.

6   The National Drug Code, as established by the

7 FDA, should be the initial data element included in the

8 barcode. This should be implemented as quickly as

9 possible. Inclusion of the expiration date and lot

10 number, especially to track recalled and out-of-date

11 products, should be added to the barcode as soon as

12 technically feasible.

13   These components can be phased in over a

14 longer period of time. Working out the technical

15 products related to the lot number and expiration date

16 should not delay the implementation of a barcoded label

17 that, at minimum, identifies the drug, its strength,

18 and manufacturer.

19   If the FDA proceeds with a rule including only

20 the NDC number, the Alliance has the technical

21 expertise and is willing to work with the FDA to

22 identify solutions and time frames for implementation.

1   The choice of symbology for the barcode is a

2   critical element of the proposed rule and should be

3   governed by specific principles. The Alliance

4   recommends that only existing symbologies utilized in

5   healthcare with the capacity to include the NDC, lot

6   number, and expiration date be used for the barcoded

7   label.

8   Additionally, symbologies appropriate to

9   pharmaceutical packaging size and capable of being

10   scanned by existing and readily available commercial

11   scanning technology should be selected. These

12   principles would allow flexibility to pharmaceutical

13   manufacturers, while providing for a level of

14   standardization for the users of scanning devices,

15   without significantly increasing their costs.

16   The placement of the barcode on packaging for

17   human drug products should be in a position where the

18   typical user of a scanning device can reliably and

19   consistently scan it. The printing quality of the

20   barcode should be at a C or better ANSI standard.

21   There should only be one unique barcode for a unit of

22   use package.

1   Hospitals have employed barcoding in their

2   administration system or automated dispensing cabinets,

3   but only after extensive repackaging of their

4   pharmaceuticals has been undertaken. This lack of a

5   preprinted barcode creates the attendant risk of

6   introduction of new error through repackaging and

7   relabeling into the medication process.

8   Medical devices: The Alliance, with its

9   strong interest in patient safety, supports the

10 eventual inclusion of certain medical devices in the

11 barcode labeling recommendation. Because of the

12 complexity of this issue, in selecting the devices to

13 be covered and the information to be included, the

14 Alliance feels strongly that the progress in labeling

15 human drug products with barcodes should not be impeded

16 by the issue related to medical devices.

17   The Alliance recommends that the FDA complete

18 its proposed rule on human drug products and biologics,

19 and then explore the feasibility of creating a barcode

20 rule for selected medical devices.

21   Benefits and obstacles: The healthcare system

22 will become safer with barcoding. Barcoding will

1   decrease medication errors. Barcoding will foster

2   progress in developing interoperability of fragmented

3   information systems. Barcoding will serve as a

4   tracking tool for medication and device distribution.

5   The Alliance recognizes that while the cost to

6   the manufacturer to place the barcode on a unit of use

7   label is not insignificant, much larger expenditures

8   will have to be made by the healthcare organizations to

9   take full advantage of barcoded medication delivery.

10   However, healthcare has always had early

11   adopters who, given the basic tools, have led the field

12   to new levels of quality and service. We expect the

13   same to happen once barcodes are widely available on

14   human drug products.

15   Time frames: Today's hearings will raise many

16   questions related to issuing a final rule requiring

17   barcoding for human drug products. Realizing the NDC

18   is the data element most easily incorporated in the

19   barcode, we encourage the FDA to move quickly in

20   establishing the requirement for barcoded labeling with

21   at least the NDC. The Alliance offers its assistance

22   to work with the FDA in identifying a specific date for

1   this requirement.

2   In conclusion, the Alliance would like to

3   thank the FDA for this opportunity to address issues

4   raised in proposing a rule on barcode labeling for

5   human drug products and biologicals. We stand ready to

6   work with the FDA, drawing on the expertise of our

7   diverse member organizations, to resolve the

8   outstanding issues related to the barcoding of drugs,

9   biologicals, and devices.

10   We are committed to a consensus approach that

11 places the patients and their safety above all

12 interests. Only through such a broad-based and

13 committed partnership will we achieve the promise of

14 high quality patient care.

15   From a personal perspective, from a CIO who

16 has the responsibility for the automation of the

17 healthcare information processes at an institution that

18 has patient safety at the core of its mission, we are

19 now positioning our environment to take full advantage

20 of barcoding technologies.

21   If this rule is adopted, we will support it.

22 We will be technically and culturally ready to

1   implement barcoding to its fullest. We will benefit

2   from its measurable results in safer care and operating

3   efficiencies.

4   We see this barcoding rule as the capstone and

5   last step in achieving a fully automated medication

6   administration process that has our patients' interest

7   and safety at its core. We firmly believe that safer

8   care will be the ultimate result for our patients.

9   Thank you.

10   MS. DOTZEL: Thank you, Tim.

11   Next we have Pamela Cipriano, who is here on

12   behalf of the American Nurses Association.

13   MS. CIPRIANO: Thank you. I am Pam Cipriano,

14   chief clinical officer at the University of Virginia

15   Health System, and am representing the American Academy

16   of Nursing and the American Organization of Nurse

17   Executives, subsidiaries of the American Nurses

18   Association and the American Hospital Association,

19   respectively.

20   As front line healthcare workers, the nation's

21   work force of 2.7 million registered nurses have made

22   and continue to make substantial contributions to

1 reduce healthcare errors. The American Academy of

2 Nursing and the American Organization of Nurse

3 Executives embrace the development of point-of-care

4 technologies that reduce medical errors and increase

5 productivity, and appreciate the opportunity to discuss

6 our view on the particular issue of barcode labeling

7 for human drug products, biologicals, and devices.

8   A few weeks ago, the American Academy of

9 Nursing, in conjunction with over 20 organizations,

10 convened an interdisciplinary conference focused on

11 using innovative technology to enhance patient care

12 delivery. Nurses, pharmacists, physicians, hospital

13 trustees, administrators, manufacturers, health policy

14 analysts, architects, software engineers, and others

15 gathered in Washington to begin harnessing the strength

16 of technology in redesigning our practice environment

17 and care delivery system in order to improve nurse

18 retention and healthcare quality.

19   Conference participants supported the

20 establishment of a system that, one, uses technology to

21 improve productivity and safety through automation;

22 two, improves medication administration processes; and

1 three, provides interactive, automatically recorded

2 data at the point of care.

3 The opportunity for error reduction with

4 barcode labeling for human drug products promises to be

5 significant. Barcodes and other machine-readable codes

6 are most effective when they are in a standard format,

7 not yet consistently found in healthcare applications.

8 Barcoding is currently available to assist in

9 the identification of patients, caregivers, specimens,

10 medications, and equipment. It further facilitates

11 automated documentation, record-keeping, billing,

12 inventory tracking, and the study of near-misses and

13 errors.

14 Ensuring appropriate medication administration

15 is a complex process involving a series of interrelated

16 decisions and actions among a variety of professionals.

17 Errors can occur at any point in the process.

18 Automated information and decision support systems have

19 proven effective in reducing many types of medical

20 errors. More specifically, barcode technology can

21 minimize the variation in the medication cycle and

22 decrease medication errors.

1   Use of barcoding automates the distribution,

2   management, and control of medications. Such

3   technology not only allows professional registered

4   nurses to more accurately and efficiently administrator

5   medications, but it also streamlines nursing's

6   workload, thus allowing more time to be devoted to

7   direct patient care activities.

8   Studies indicate that barcode labeling of

9   drugs in acute care settings can prevent over 7,000

10 deaths a year and save nearly $5,000 per admission.

11   Further development and wide scale deployment

12 of barcoding require the healthcare industry to address

13 issues of standardization of code technology,

14 compatibility, reliability, and affordability. Keys to

15 the successful application of such technology include,

16 one, ensuring end users are involved in the process

17 from the beginning; two, creating integrated systems

18 that do not require reentry or rekeying of data; and

19 three, reducing the workload burden.

20   While the literature indicates that the

21 mandated use of barcode labeling for human drug

22 administration can provide substantial benefits to the

1   quality and safety of patient care, there are certain

2   aspects in the implementation of this technology that

3   require further consideration. And these are patient

4   populations, standardization, compatibility,

5   reliability, and financial considerations.

6   Children are a population at risk for errors.

7   The IOM noted that a four-year prospective study found

8   350 medication errors resulting in injury among over

9   2,000 neonatal and intensive care admissions. Many

10   pediatric doses are nonstandard and are prepared

11   internally by the pharmacy. A mechanism for adding a

12   barcode to institution-specific medications increases

13   the cost of dose preparation and adds time.

14   Infant identification also presents challenges

15   to barcoding for identification, given the tiny size of

16   the limbs and the ID bands. Systems that link mother

17   to baby may have barcode labeling for the mother but

18   only manual identification for the infant. So the full

19   benefit of the technology is not realized.

20   A second area for further consideration is the

21   standardization of barcode terminology. While we are

22   pleased with forward movement toward developed

1   appropriate standards for information exchange, the

2   data and technology must be acceptable across various

3   settings.

4   Nursing joins other organizations in support

5   of the recommendations of the National Coordinating

6   Council for Medication Error Reporting and Prevention

7   that you have heard previously, which asks for the

8   National Drug Code, NDC, lot, control, batch number,

9   and expiration date at the unit of use package.

10   Barcoding of drugs should also be possible for

11   nonstandard items at minimal cost to the dispensing

12   pharmacy. This would include such preparations as

13   ointments, lipids, TPN, manually prepackaged items,

14   crash cart supplies, et cetera. Labeling of blood

15   products should contain the donor, blood type, blood

16   product, and attended patient, at a minimum.

17   Administration of a drug or therapy would also

18   be guided or assisted with barcoding of the patient's

19   identification data. Wristbands with barcoding can

20   prevent any error by alerting the caregiver to a

21   mismatch between the patient and the intended drug or

22   treatment.

1   Implementation of barcodes for medication

2   control often succeed in decreasing errors related to

3   wrong dose, wrote time, omitted dose, and transcription

4   or order entry. One Colorado hospital saw a drop of

5   over 50 percent in different types of medication errors

6   after implementation of their point-of-care information

7   system for medication management.

8   Bedside medication verification products have

9   been on the market as a complete system for two years.

10   However, some of these systems are still very

11   cumbersome. Nurses need a reliable, accurate, and

12   rapid system that reduces workload and is more

13   efficient or faster than a manual one.

14   One hospital discovered it had an eight-second

15   delay in medication recognition and reconciliation with

16   the patients' database. Until discovered through

17   investigation of a medication error, this unacceptable

18   delay was determined to be causing the nurses to

19   circumvent the system. Nurses can be masterful at

20   finding ways around systems when they don't work to

21   their benefit. I must emphasize the importance of

22   involving end users in the development and

1   implementation phase of this technology.

2   It is also desirable that manufacturers and

3   suppliers of drugs and biological products provide 100

4   percent of products with barcoding. This will ease the

5   workload of not only nurses but also pharmacists, also

6   in short supply in the current and future workforce.

7   Implementing standards for barcoding will

8   introduce some challenges for existing equipment.

9   Systems need maximum flexibility to support both

10   existing handheld scanner technology as well as other

11   machine-readable formats.

12   Right now many organizations are challenged

13   with having incompatible identification technologies.

14   For example, a blood gas analyzer that is equipped to

15   read the magnetic identification strip on the caregiver

16   testing the specimen cannot read the patient

17   identification system if it is in barcode format and if

18   the machine has not been adapted for this scanning

19   technology. Therefore, again, we don't have complete

20   data capture.

21   The location of barcode labels on drugs needs

22   to be adaptable to current technology, such a robots,

1   that pick medications and fill medication parts, again,

2   dealing with the rewrap and overwrap issue. Transition

3   to future two-dimensional codes will also require a

4   bridge from existing to new technology. These codes

5   are very promising, with high data density, redundant

6   data, low contrast reading, and easy writing on

7   conventional printers.

8   Further, the reliability of scanners to read

9   the barcode is critical to the success of such

10 technology. It has been found that some bar scanners

11 cannot read curved surfaces. Since almost all

12 identification bracelets are on a wrist, valuable time

13 can be spent flattening out the identification band to

14 allow the scanner to recognize it, often requiring as

15 much time as would be spent administering a medication

16 without benefit of technology.

17   Finally, we must raise the issue of

18 affordability and financing of such technology.

19 Clearly, the cost of implementation in practice

20 settings will vary based on each institution and the

21 structural changes required to manage the point-of-care

22 systems.

1   Manufacturers and suppliers must share in the

2 production of materials that respond to the mandate for

3 safety and address workload burden. Collectively, we

4 had a duty to reduce error and prevent avoidable

5 adverse events.

6   Barcode labeling has proven beneficial for

7 other advantages such as charge capture, billing,

8 record-keeping, inventory tracking and control, and

9 automated documentation for patient records and quality

10 improvement review.

11   In conclusion, we applaud the FDA's efforts to

12 improve patient safety and reduce the number of adverse

13 drug events due to medication errors. Barcode labeling

14 for human drug and biologic products is one means of

15 applying simple technology to a broad spectrum of high-

16 risk processes and realizing a significant safety

17 impact. Thank you.

18   MS. DOTZEL: Thank you, Pamela. And then

19 last, from the American Hospital Association, we have

20 Dr. John Combes.

21   DR. COMBES: Good morning. My name is John

22 Combes. I'm the senior medical advisor to the American

1 Hospital Association and the Hospital and Health System

2 Association of Pennsylvania. I'm here today on behalf

3 of AHA's 5,000 member hospitals, health systems,

4 networks, and other healthcare providers.

5   We are very pleased to testify today on an

6 issue that promises to improve patient safety, the

7 barcoding of drugs, devices, and biologicals. I also

8 represent AHA on and currently serve as chair of the

9 National Coordinating Council on Medication Error

10 Reduction and Prevention.

11   NCCMERP, as it is fondly known as, recently

12 offered a series of recommendations on the

13 implementation of uniform barcode standards, down to

14 the unit of use level, for all pharmaceutical product

15 packaging. The AHA, as a founding member of the

16 council, supports those recommendations and desires to

17 work with the Food and Drug Administration and other

18 interested parties in the successful implementation in

19 America's hospitals.

20   NCCMERP's recommendations for barcoding of the

21 unit of use medication offers a good starting point for

22 the development of regulations for labeling standards.

1   The recommendations identify the minimum data to be

2   included in the barcode, labeling and format

3   parameters, and suggest which packaging should be

4   barcoded.

5   The council recommends the expeditious

6   implementation of barcode labeling standards by the FDA

7   in collaboration with the U.S. Pharmacopeia and the

8   pharmaceutical industry. However, the council also

9   recognized that the use of barcoding technology as a

10   mechanism to improve medication safety should be

11   implemented incrementally, with careful planning and   ·

12   giving thoughtful deliberation for cost, cultural, and

13   implementation issues.

14   The AHA supports the FDA's efforts to require

15   a barcode on the label of human drug products down to

16   the unit of use packaging. Stakeholders still need to

17   identify what products should be labeled with a

18   barcode, what data should be included in the barcode,

19   and what symbologies should be employed.

20   However, the general principle of including

21   the barcode as an integral part of the label is

22   supported by hospitals and health systems. We should

1   not wait until all the details are worked out for

2   barcoding drugs, devices, and biologicals before

3   instituting change.

4   Today's public meeting should help identify

5   what can be done rapidly and what steps will require

6   additional time. The FDA's regulation should codify

7   what is doable now, and the FDA and healthcare industry

8   together should develop a plan that will lead to the

9   timely phase-in of barcodes on devices and other

10 medical products for which we cannot implement

11 barcoding immediately. The AHA stands ready to assist

12 the FDA in these efforts.

13   Now I'll turn my attention to some of the

14 questions raised by the FDA in their announcement of

15 this meeting in the Federal Register.

16   The AHA supports the timely phased-in

17 implementation of a requirement for barcode labeling

18 beginning first with human drug products, both

19 prescription and over-the-counter drugs. This approach

20 allows for the development of bedside scanning

21 capabilities in hospitals, which will enhance patient

22 safety in the administration and dispensing of

1 medications.

2 Additionally, for those hospitals and health

3 systems that already use bedside scanning, it will

4 reduce the need for repackaging of medications,

5 eliminating another potential source for medical error.

6 Following the labeling of human drug products, the FDA

7 should also mandate the barcode labeling of vaccine and

8 blood products.

9 Adamant among the barcode should include the

10 National Drug Code, the NDC number, as established by

11 the FDA. Including the expiration date and lot number

12 would also be beneficial and desirable, especially to

13 track recalled products.

14 But there may be technical and cost issues

15 that make this less feasible immediately. Resolving

16 the technical problems related to the inclusion of the

17 lot number and the expiration date, however, should not

18 delay the implement of barcode label that, at a

19 minimum, identifies the drug, its strength, and the

20 manufacturer.

21 If the FDA proceeds with this rule, including

22 only the NDC number, it should explore with the field

1   other ways for the lot number and expiration date to be

2   available at the bedside.

3   It is important to recognize that hospitals

4   have already made a significant investment in scanning

5   technologies for clinical care and inventory control.

6   Any symbology adopted by the FDA for barcodes should be

7   compatible with current scanning devices used by

8   healthcare organizations. Symbologies requiring

9   optical scanning should not be mandated since this

10   would require the wholesale replacement of current

11   information systems at a significantly increased cost.

12   Barcodes are currently being used in hospitals

13   for laboratory specimen identification, blood and blood

14   products, inventory control, and automated dispensing

15   cabinets. Some hospitals use barcodes in their

16   medication administration systems, but only after

17   extensive repackaging of their pharmaceuticals, which

18   increases the possibility of medical error.

19   The major obstacle to the more widespread use

20   of barcoding to improve patient safety is this lack of

21   the preprinted barcode on the unit of use dose.

22   Barcodes should be required on all packaging and

1 containers down to the level of use just prior to the

2 administration of the product to a patient.

3 One of the most significant factors in

4 reducing medication errors is the ability to identify

5 the right drug and the right dose administered to the

6 right patient. By including the barcode on the

7 packaging used for the administration of the drug at

8 the bedside, the right drug and the right dose can be

9 easily identified.

10 The next step in a phased-in implementation of

11 barcoding standards would be applying the technology to

12 medical devices. The AHA supports the labeling of

13 certain medical devices with machine-readable codes.

14 This can improve patient safety by allowing the

15 tracking of device failures, device-related infections,

16 and unexpected outcomes related to the proper and

17 improper uses of the device.

18 But not all medical devices need to be tracked

19 in this way. Certain simple devices, such as bandages,

20 tongue depressors, and crutches, may not require this

21 type of labeling. Prior to the FDA proposing a rule

22 for the labeling of devices with machine-readable

1   codes, studies should be undertaken to determine which

2   devices labeled with barcodes would have the most

3   impact on improving patient safety.

4   We should really look at our devices and

5   stratify them according to the risk to the patient, and

6   only those that pose the highest risk should be the

7   ones that are barcoded. However, these studies should

8   not delay the FDA from implementing a rule for the

9   labeling of human drug products with barcodes.

10   A label for devices should include a unique

11 identifier, which contains information on the specific

12 manufacturer of the product and possibly the lot

13 number. The FDA should establish a separate process,

14 and perhaps a separate public meeting, to address the

15 issues around the labeling of devices. Additionally,

16 any labeling format should be consistent with what is

17 established by the FDA's rule for the labeling of human

18 drug products and biologicals.

19   The AHA encourages the FDA to have a planned

20 process for the implementation of barcoding, beginning

21 with drugs and blood products. At the same time, the

22 FDA should start the process for identifying what

1 devices should be barcoded and what information should

2 be contained in those particular barcodes.

3 Medication errors are a critical concern for

4 everyone involved in healthcare. We must build systems

5 that make sure the right patient is getting the right

6 medication at the right dose at the right time.

7 Barcoding technology can greatly enhance patient safety

8 by ensuring there is a realtime verification of the

9 correct patient, medication, dose, and time.

10 And hospitals are committed to using the best

11 available technology within their resource capacity to

12 improve patient care and reduce medical errors. We

13 must recognize that placing a barcode on the label of

14 human drug products is only the first step in creating

15 a safer medication delivery system. Hospitals must

16 have information systems in place, complementary

17 technology, and trained personnel to create a safer

18 system.

19 To maximize patient safety and to take full

20 advantage of the information available from using

21 barcodes, such a patient alerts about dosage limits,

22 drug/drug interactions, drug/food interactions, and

1 allergies, hospitals and health systems must make

2 significant investments.

3 The incompatibility of current information

4 systems is an obstacle and a disincentive in hospitals

5 that would need to make significant investments to put

6 such systems in place. Can compatible systems be

7 created in hospitals? Is technology stable enough to

8 endure over time? Are hospitals investing in

9 technology that will be quickly obsolete? These

10 incompatibilities and questions are a major source of

11 the costs associated with the use of the unit of use

12 barcode.

13 In addition, hospitals face other costs, such

14 as staff training in the use of barcodes and scanning

15 and bedside scanning, and repackaging and labeling of

16 extemporaneous preparations.

17 Finally, to improve medication safety through

18 point-of-care barcode scanning, hospitals will need to

19 establish a radio frequency backbone inside the

20 hospital so that wireless devices may be used, without

21 which many of the efficiencies of barcoding are lost.

22 Recently the AHA convened multiple

1   stakeholders interested in standardizing healthcare

2   information technology. And you heard earlier from Tim

3   Zoph from the National Alliance of Health Information

4   Technology. I have the latest numbers. We are now

5   over 60 organizations, representing providers,

6   purchasers, manufacturers, and standard-setting

7   entities.

8   The Alliance mission is to mobilize the field

9   to address the fragmentation and lack of coordination

10   in healthcare, improving quality and performance

11   through standards-based information systems. The

12   Alliance's first initiative is to promote the use of

13   barcoding in creating a more efficient and effective

14   system of healthcare.

15   The AHA has demonstrated its commitment of

16   working with all stakeholders on this very important

17   issue by being involved with the Alliance and helping

18   to create the Alliance. It is our desire to move

19   forward with the FDA and other interested stakeholders,

20   including pharmaceutical manufacturers, device

21   manufacturers, group purchasing organizations, to

22   implement quickly this requirement for barcode labeling

1   of human drug products, and then to move as

2   expeditiously as possible to the labeling of certain

3   medical devices, blood, and other biologics.

4   I want to thank you for the opportunity for

5   the AHA to speak before you. We are committed to

6   improving patient safety. And with all your help, we

7   can advance the science of patient safety and assure

8   better outcomes for all our patients. Thank you very

9   much.

10   MS. DOTZEL: Thank you, John.

11   Now I'd like to ask members of the FDA panel

12   if they have any questions they'd like to ask our

13   health professional panel.

14   Dr. Crawford?

15   DR. CRAWFORD: Yes. A clarification from

16   Kasey Thompson. I believe you said approximately

17   1 percent of hospitals use barcoding. Is that correct?

18

19   MR. THOMPSON: Yes. An ASHP national survey

20   conducted in 1999 --

21   VOICE: We can't hear you.

22   MR. THOMPSON: The microphone doesn't appear

1 to be on. An ASHP national survey conducted in 1999 of

2 about 5- to 7,000 hospitals determined that only about

3 1.1 percent of those institutions currently use

4 machine-readable coding technology to verify drug

5 administration by the provider at the bedside.

6   DR. CRAWFORD: And is it your understanding

7 that that is increasing, or remaining the same, or do

8 you know?

9   MR. THOMPSON: My guess, and we'll have up-to-

10 date data in the next few months, is that it's probably

11 not increasing significantly because the product's not

12 available. The fact that there's very few products

13 available in unit dose packages with a barcode on it at

14 this point in time doesn't provide a lot of incentive

15 to hospitals at this point to purchase the technology.

16   I think once we get the technology available

17 and the tools are there, meaning the unit dose packages

18 with the barcode, you'll see the number of hospitals

19 using the technology increase dramatically.

20   DR. CRAWFORD: And secondly, I'd like to ask a

21 question of the entire panel. And that is is that what

22 we are proposing is a regulation to cover the issue of

1   barcoding. And what we are about here is trying to

2   figure out what should be included within that.

3   I take it you are all in favor of the

4   regulatory approach?

5   MR. THOMPSON: Yes.

6   DR. CRAWFORD: Anyone not in favor?

7   (No response.)

8   DR. CRAWFORD: This is a first in my many

9   years of -- I am going to retire at this point.

10   (Laughter)

11   DR. CRAWFORD: Dr. Combes, you did say that it

12   should be phased in, and over about how long a period.

13   One of the problems with phasing in is that, you know,

14   we run the risk of losing momentum, and we believe this

15   is very important from a public health point of view.

16   So I'd like for you to elaborate on that, if

17   you wouldn't mind.

18   DR. COMBES: I think that after consultation

19   with some of the pharmaceutical manufacturers, we

20   should be able to get the barcode onto the label of

21   unit of use packaging with at least the NDC number

22   almost immediately. I mean, I think there really

1   shouldn't be much delay in doing that. In fact, we had

2   an announcement from one of the major pharmaceutical

3   companies the other day that they would be doing that

4   in the future. And so I think we can get there.

5   There are some issues that we need to work on,

6   technical issues about getting the lot and the

7   expiration date. But I don't think those should take

8   longer than a year to 18 months. I think the biggest

9   problem is going to be with devices because we really

10   do need to stratify the devices. Not all devices will

11   need a universal product number or a barcode.

12   But there are certain devices which it would

13   be very helpful to track when we have device failure,

14   and particularly infections. I mean, we all are very

15   familiar with the cases of the bronchoscopes up at

16   Hopkins, and things of that nature, where you can go

17   back and really hone down into what might be the

18   problem. And that also gets into when we look at the

19   sterilization of devices and the use of devices --

20   multiple uses of a single device.

21   DR. CRAWFORD: Thank you.

22   FDA PANELIST: I'd like to ask the panel a

question that you probably could each talk about for

ten minutes. But just very, very briefly, what would

you identify as the single biggest problem or

impediment or concern about an FDA regulation in this

area? The single biggest problem?

DR. COMBES: I'll take a shot at it. I guess

if the regulation was overarching and didn't hear the

concerns of the industry in terms of what was included

in the regulation. But I think if we took a phased-in

approach, there are things I think we can, as I just

said, do right away, and are considerate of what

technologies already exist in healthcare organizations.

I think that will work well. And I think if

you work cooperatively with providers and

manufacturers, we can get there. What we would hate to

see is somebody say, we need to have data matrix codes

or other kinds of codes on the label that we would have

to change all our scanning devices and do a whole lot

of retraining.

MR. THOMPSON: Well, I think you heard great

agreement at this table that an FDA mandate is an

absolute requirement at this point. It's been clear

1   for years and years that this wasn't going to be

2   something that the industry was going to do on a

3   voluntary basis.

4   So it really -- at this point in time, I think

5   that the, you know, negative effects of an FDA mandate

6   are very minimal. I mean, this needs to be done.

7   There probably isn't a person in this room who hasn't

8   experienced a medication error themselves or had a

9   family member who has.

10   I mean, we're not talking about new technology

11   here. We're not developing flying cars or alternative

12   fuel sources. This is technology that's currently

13   available now, and it's achievable. There's

14   manufacturers testing it. They've said they can do it

15   and include all three data elements. So it's there.

16   MS. CIPRIANO: I think one of the biggest

17   concerns, however, is the implementation of a complete

18   system. And probably the biggest fear is cost,

19   particularly as we look at how broadly across our

20   healthcare delivery system would these requirements be

21   required -- in other words, nursing homes, the home

22   care environment, outpatient environment where

1 typically we may have the same conditions existing in

2 someone's own home that exist in some of these other

3 low-intensity, low-risk environments.

4 So I think the biggest fear would be how

5 sweeping would this requirement be; how quickly would

6 the costs need to be incurred to have a system that not

7 only provided identification of the drug in the

8 dispensing end of the system, but also the match to the

9 patient identification; and recording and looking for

10 any kind of alerts in the system.

11 DR. CRANSTON: Yes. I think, from the AMA's

12 perspective -- and we're going to be very flexible on

13 this issue because we certainly are not the experts --

14 but I think that the benefits of a proposed rule or a

15 final rule clearly outweigh the risks, I think.

16 But I think the problem side is that sometimes

17 when FDA issues a rule, you know, kind of everything

18 stops. And so, you know, the future innovation, ways

19 to improve the system, you know, might be impeded.

20 So I think that you have to take that into

21 consideration as you're putting together this rule so

22 that we can get something out there quickly that's

useful that cause the hospitals to really want to take

advantage of it, but at the same time, you know,

there'll be means to improve the system in the future.

MR. ZOPH: Yes. I would just make the point,

and you can tell from my testimony that the biggest

challenge may be setting forth a rule and still having

some unanswered questions related to medical devices

and other evolving standards.

So I think that may be a challenge in terms of

knowing that a rule may come forward and there is more

work to be done. However, I believe that is absolutely

the right thing to do.

FDA PANELIST: Much of the emphasis has been

on the importance of these systems in hospitals. But

an issue that's come up from time to time with recalls

has been the changing practice of pharmacy. At one

time in some states, it was required for pharmacists to

write lot numbers on prescriptions and to track that.

But as I understand it, most states have dropped that.

Would anyone care to update on the role that

you see for barcoding in prescription drug containers

given to the patient in an outpatient setting for

1 medications at the home? Is this something also that

2 is something that should have benefits, or is this just

3 a nice to have thing which shouldn't be required?

4   MR. THOMPSON: Well, I think something that's

5 very clear in our interest here, and I think in the

6 interest of patients, is that all pharmaceutical

7 products contain a barcode. And, you know, we

8 emphasize that that go all the way down to the single

9 unit unit dose package.

10   We need to be very careful in some of the

11 nomenclature on this as well. We're using unit of use

12 and unit dose somewhat interchangeably. They're not.

13 I won't get into the details of that.

14   But a single unit unit dose package is a

15 package that contains a single drug in one individual

16 package. A unit of use package is, for example,

17 something like a package of oral contraceptives or a

18 Medrol dose pack that has a specified series of doses.

19 But you can look at the USP on that one. I won't get

20 into a lot of detail.

21   But the key point here is the manufacturers be

22 required to place barcodes on all pharmaceutical

1 product packages.

2 FDA PANELIST: But I guess my question is,

3 would that extend to when the pharmacist, outpatient

4 pharmacist, prints a label for that little amber-

5 colored plastic bottle you take home? Does that

6 barcode go on that for future reference as well? Do

7 the pharmacists now track lot numbers to patients in

8 the outpatient setting as well, or do you see this

9 largely as an initiative that is primarily needed in

10 the inpatient?

11 MS. CIPRIANO: I believe it needs to be

12 extended to outpatient. What we find is that there are

13 already -- up to 70 percent of patients never take

14 their drugs correctly. So the barcodes aren't going to

15 help with that part of the problem.

16 But I think if we're absolutely certain that

17 we've done the correct identification, and then if a

18 patient comes in and we are trying to track back any

19 problems with those medications, or if we have recalls

20 just like we record -- we do record lot numbers for

21 samples of drugs that are dispensed in outpatient

22 clinics and things like that. I think the more

1   information that is available, if there is any untoward

2   effect, the better our management of those medications.

3

4   DR. COMBES: Actually, this issue came up in

5   some discussions we were having several weeks ago. And

6   we all kind of sat around and said, well, we didn't see

7   how a patient would benefit in their home with a

8   barcode on their medication label.

9   And somebody said, given how technology has

10   advanced so rapidly in this area, particularly with

11   handheld devices, one could imagine that a patient

12   would maintain their own individual medication

13   administration record at home, particularly patients

14   who have complex drug regimens, and could actually,

15   with the use of a PDA, scan their medications to make

16   sure that they're taking the right medication at the

17   right time.

18   So I think it might be shortsighted of us to

19   dismiss that these would have any application in the

20   home setting. And I think, you know, this is America,

21   where there's an opportunity if somebody will come up

22   with a device and make it work. So I think we should

1   consider that as we go forward.

2   FDA PANELIST: The other application that

3   occurs to me is that on refills, the patient brings the

4   product back. The pharmacist could rescan the label,

5   see if they're actually dispensing the same medicine

6   before -- make sure you don't have a name lookalike-

7   type problem.

8   MR. THOMPSON: Let me just make one more point

9   to address your question about the capability and the

10   usefulness in the ambulatory sector. It would be very

11   useful, and you addressed the point of should be this

12   on product labels, meaning the actual prescription file

13   you get.

14   Well, actually, if the lot number and

15   expiration date and NDC were contained in the barcode,

16   it would scanned in the pharmacy and then populated

17   into a database there in that pharmacy. So you'd be

18   able to identify patient with product dispensed and,

19   you know, know who you gave a certain lot number to.

20   So I'm not advocating for or against putting

21   this on an actual prescription vial but, you know, you

22   would be able to do that through technological means

1   that way.

2   And with vaccines now, it's currently a

3   requirement, I think, federally that we record lot

4   numbers and expiration dates for all vaccines that are

5   given. So it would be useful there just to be able to

6   scan a barcode on the product and have that populated

7   database.

8   FDA PANELIST: I have a question. All the

9   panel members think that all three elements of the

10   barcode that we've asked about should be in there, and

11   some have said that a staggered implementation or

12   incremental approach would be good.

13   Ms. Cipriano and Mr. Thompson, you advocated

14   all three pieces, but didn't say anything about how it

15   should be done. Do you see value in getting something

16   like the NDC code on there as soon as possible, as

17   opposed to delay for all components?

18   MR. THOMPSON: Well, clearly, the NDC is the

19   most important element that would identify the drug and

20   the dose and, you know, the specific product. So

21   clearly, that absolutely positively has to be in the

22   product.

1   Now, my concern is that with lot number and

2 expiration date, that we not just let this fall by the

3 wayside and delay it for five or ten years. If a

4 tiered approach is needed to do that to get the

5 industry, you know, in gear to do that, then that is

6 fine.

7   I do know that there are pharmaceutical

8 companies out there now that are testing this and have

9 told me in private conversation that it's achievable to

10 include lot number and expiration date and print on a

11 high-speed production line at this point in time.

12   Now, if there needs to be some kinks worked

13 out in that, fine. But let's not take too long to

14 actually implement that and require that.

15   MS. CIPRIANO: I would agree. I think we need

16 to move forward so that we can begin to implement the

17 use of at least the NDC, as has already been supported

18 by FDA.

19   FDA PANELIST: I have a question for

20 Mr. Combes -- or Dr. Combes. I apologize. You spoke

21 about a staggered implementation, and suggested first

22 drugs and then biologic -- or vaccines, at least, and

1   blood second.

2   And my question to you is, given that, for

3   instance, in the blood area, there already is some

4   barcoding going on, what would be your justification or

5   rationale for waiting for that, for those products?

6   DR. COMBES: Again, I think it's so we don't

7   lose focus on the human drug products. Because that is

8   something that there really hasn't -- hospitals and

9   other healthcare organizations haven't taken advantage

10   of because they haven't had the barcode.

11   In blood, it's my understanding that there are

12   recommended standards, but no required standards out

13   there around it. And there is some concern about the

14   technology or the symbologies that were used for blood.

15   And that may need to be investigated in terms of which

16   symbology to choose for blood and what are the data

17   elements as you go through a mandate.

18   I think that's going to take you a longer

19   period of time than it would be to say, let's have the

20   NDC number in the barcode on the label by January 1st.

21   I think there's a little bit more investigation that

22   has to be done. There has to be a lot more work with

1   the blood suppliers on that issue. And there has to be

2   a resolution of the issues around symbologies, from my

3   understanding.

4   FDA PANELIST: And just to pick up on that,

5   and this is, I guess, for the whole panel, what I'm

6   hearing people talk about is a lot of support for use

7   of the NDC. And I think, Dr. Combes, you're the only

8   who has sort of just mentioned the difference between,

9   you know, sort of what's happening with blood products

10   and the others.

11   I don't know if the rest of you have thought

12   about the use of the NDC for blood products, given

13   what's currently happening in blood. I believe they're

14   not using the NDC now, and yet do some barcoding.

15   And then finally, my last question is for Tim

16   Zoph. You talked about the data 35 percent, if I

17   understood right, of medicines at the bedside are

18   barcoded?

19   MR. ZOPH: Yes. We --

20   FDA PANELIST: If you can just tell me. And

21   then, you know, you can add to that. But who's doing

22   that barcoding? Is it the hospital? Is it the

1 manufacturer?

2   MR. ZOPH: We have -- what our experience is,

3 again, the data, our evaluation of that is

4 approximately 35 percent today of unit of use

5 medications come in with a barcode. We actually

6 repackage about 1 percent.

7   One of the points I'd make on this, too, on

8 the repackaging because I know that has come up, we

9 looked at what it would take for us to repackage all

10 those medications that don't come in with a unit of use

11 barcode.

12   And if you look at the error rate introduction

13 into the process, if we give 2-1/2 million doses a

14 year, and even if we take a ten-step process, assuming

15 we can hit, say, a 99.9 percent effectiveness, we're

16 going to introduce 70 new errors a day just from

17 repackaging. So that's one point that I would make.

18   The other observation I'd make is that our own

19 experience is that because unit of use packaging is a

20 small part of the pharmaceutical business, and you may

21 hear about this from the manufacturers this afternoon,

22 is that we're actually seeing some decrease in the

1 actual packaging of unit of use into our institutions.

2 So it's not only the label, but it's also the packaging

3 that's occurring.

4   FDA PANELIST: But I'm still not -- who is

5 putting the barcoding on? The VA talked about they did

6 the barcoding themselves -- I don't know if that was

7 correct -- as opposed to is anyone else doing that?

8   MR. ZOPH: Yes. We have manufacturers who are

9 putting barcodes.

10   FDA PANELIST: Manufacturers?

11   MR. ZOPH: Yes.

12   FDA PANELIST: And how are you using those

13 barcodes?

14   MR. ZOPH: Well, that goes to the core of it,

15 is that unless we get to the point where we have such a

16 high volume of barcode where we can introduce it in a

17 reliable way into the process, that barcoding doesn't

18 really serve a purpose for us now because we have a

19 smaller number of products coming in with a barcode.

20 So therefore, we've got to get to a much higher

21 penetration of those barcodes coming into the

22 institution before we can introduce it in a reliable

1   and predictable process.

2   DR. COMBES: There's a lot of repackagers out

3   there and distributors that will barcode medications,

4   particularly when you have automated dispensing carts.

5   Those are generally repackaged with a barcode on them

6   so that you can take advantage of those carts. So that

7   would be one example.

8   FDA PANELIST: Can I just another question,

9   then? If they are repackaging and putting a barcode,

10 is there some sort of standardization right now with

11 regard to what is on those because? The NDC number?

12 The expiration date? The lot number?

13   DR. COMBES: I think they all have the NDC

14 number on them. But beyond that, I'm not sure that

15 there's any standardization, and it would depend on the

16 repackager and it would depend on the distributor that

17 was doing it.

18   Many of them are done by vendors of those

19 automated systems, who supply the -- will repackage the

20 drugs for you as part of their contract with you to

21 have that automated system within the hospital. So

22 they really do it for the purposes of their own devices

1 rather than have a universal standard that everybody

2 would follow.

3   FDA PANELIST: Just following up on that, I'm

4 assuming, then, these various readers that the

5 hospitals have can read all of these different barcodes

6 that might be unstandardized?

7   DR. COMBES: It's a little confusing, to say

8 the least. Clearly, there are two levels of scanners

9 that you can be concerned about. One is to move into

10 optical reading devices. Those are very, very

11 expensive scanners. They read the data matrix codes,

12 which you can get barcodes in.

13   Now, there are linear scanners now,

14 particularly the latest generation of linear scanners,

15 that can be programmed up to read composite code. So

16 you could read a linear code and the composite that

17 they have the lot number and the expiration date in it.

18 So a lot of the RSS codes can be read by these.

19   Some of the older scanners can't do that, and

20 they theoretically could be upgraded but there may be

21 problems in upgrading them. But the point is, most of

22 these scanners have maybe a four- to five-year half

1 life or full life, and they get replaced over time.

2 And the current generation of scanners can read almost

3 anything other than moving to the optical scanning

4 level.

5   So in terms of symbologies, you can really

6 program the scanners to read almost anything if you

7 tell them what to read, or you tell them that's a

8 potential being out there.

9   FDA PANELIST: Let's assume that the rule goes

10 into effect or that the NDC code is on all products at

11 the unit dose a year from now. How quickly would you

12 expect hospitals and the hospital pharmacies and other

13 healthcare providers to adopt or to purchase the

14 technology, invest in the technology, to scan it and

15 start actually reaping the benefits? What would be the

16 time horizon after that that you would expect to see

17 those kinds of benefits?

18   MR. ZOPH: I'd be happy to take this. I think

19 one observation I have for you now is that hospitals

20 are, as you know, working very aggressively to

21 implement computerized order entry. And as the studies

22 show, that's obviously a very high point of error in

1   the system.

2   I do think by getting a standard out there, it

3   will allow the providers of information technology

4   solutions to understand that there is a standard and

5   begin to develop those solutions, get them integrated

6   into their electronic medical records so that the --

7   you know, a very quick add-on phase or subsequent phase

8   of that, then when the barcode is available,

9   institutions can begin to adopt and implement it.

10   There is a period of time for which you need to pull

11   together the technology community behind a common

12   standard.

13   And I think the other thing it allows us to

14   address as well is that there's a lot of benefit from

15   things other than the medication scanning at the

16   bedside, things like specimen collection.

17   And those of us in hospitals that have been

18   really trying to understand how many different devices

19   and scanning devices do we need at the bedside, and so

20   on and so forth, it allows us to begin to take a look

21   at scanning technology as a more universal tool at the

22   bedside, and begin to work with our vendor community to

1 say, we want one device. It needs to be able to read

2 these scanning technologies, and begin to work

3 importantly with the whole cultural point of care

4 setting that says, you know what? We can deal with

5 medications, laboratory specimens, other material

6 products, and have more universal solutions.

7   So we would be working aggressively in the

8 meantime, once a standard is announced, to make sure

9 that the products begin to get in the development life

10 cycle within the technology community so when it's

11 available, early adopters in the industry will be able

12 to take advantage of the technology.

13   MR. THOMPSON: I think if you combine the FDA

14 mandate that manufacturers do this and include the

15 necessary data elements, and assuming that

16 manufacturers continue to produce an enhanced

17 production of products in unit dose packages, and

18 provide that incentive to hospitals and healthcare

19 organizations, that you'll see them adopt this fairly

20 quickly.

21   Now, let's move out and look and see the

22 demand for patients and the marketplace out there.

1   We've seen groups like leapfrog, say, you know,

2   implement CPOE. They haven't said barcoding yet. But

3   there'll be incredible market pressures out there by

4   patients and others and private sector initiatives to

5   tell hospitals to do this.

6   I mean, this is important in enhancing patient

7   safety. But we've got to have the product available,

8   and it has to have a barcode on the product package.

9   DR. COMBES: One of the by-products of having

10   the rule, and I think this is why we're most interested

11   in having the rule, is it will bring to our awareness

12   our inability to get our hospital systems to

13   communicate to one another.

14   The barcode will be only of an advantage if we

15   can have patient information systems, laboratory

16   systems, decision support systems, and other systems

17   all linked together so that we can leverage the barcode

18   to really make sure it's the right drug to the right

19   person at the right time with no contraintroductions

20   and no incompatibilities.

21   And that is only going to happen -- that is

22   the long-haul process. That's only going to happen

1 when we start to develop more universal standards about

2 how we use information technology in healthcare in the

3 first place.

4   So I think, by the FDA taking this step, you

5 can really push forward the industry in really

6 seriously looking at how to capitalize off the

7 advancements in information technology.

8   We heretofore have not done that, and I think

9 this will help us. Because as Kasey said, there's

10 going to be a tremendous amount of public pressure when

11 they see the barcode on the label: Why are you not

12 using it? And we will have to turn around to the

13 people we work with and say, how come we can't use it

14 in an effective way? We need to sit down together and

15 work on some standards on this.

16   MS. CIPRIANO: I want to just elaborate on

17 what John just said. The biggest difficulty is not

18 getting a scanner. It's not acquiring the barcoded

19 drugs. It's not putting the barcodes on yourself. It

20 is having that information then be used at the point of

21 care.

22   And that's really where the cost issues come

1   in, and that's where the time delay is, that if there

2   is a mandate, most organizations -- and if we are

3   thinking primarily hospitals and locations where

4   patients are at higher risk -- the lead times for those

5   kinds of changes can be no less than two years.

6   It's not an issue of philosophy, of safety, of

7   things like that. But the practicalities right now, in

8   terms of planning for technology, where there's either

9   absent any other technology or information technology

10 or in trying to look at getting systems to communicate,

11 is just extremely taxing both timewise and financially.

12

13   MS. DOTZEL: I have two questions. One's a

14 follow up question. I heard someone way -- I can't

15 remember now if it was Tim or Kasey -- that right now

16 manufacturers are not making a lot -- and I don't know

17 whether the proper term is unit of use or unit dose,

18 the individually packaged products that you oftentimes

19 see in the hospital setting.

20   And my question is, to the extent that I

21 think -- I would assume that type of packaging is more

22 expensive, and then you add barcoding to that type of

1   packaging, which makes it even more expensive, is there

2   a concern on your part that we might be creating even

3   greater disincentive for manufacturers to package that

4   way?

5   MR. THOMPSON: That's a real concern that we

6   have. One thing I mentioned when I was speaking was

7   that the unit dose drug distribution system has very

8   good science behind it that it improves patient safety.

9   And fundamental to that system is having products in

10 unit dose packages.

11   Now, you combine a barcode with that, and the

12 ability to add that extra layer of safety and

13 protection and assurance for that nurse at the bedside

14 that's giving the personal the medication that they're

15 giving the patient the right medication, with all the

16 five rights and everything, you have very powerful

17 patient safety improvement.

18   There's a real concern out there that you've

19 pointed out that we don't want to see an adverse effect

20 of a rule becoming an industry -- I'll say excuse not

21 to produce products in unit dose packages. There's

22 science behind the unit dose drug distribution system.

1   It's effective at improving patient safety, and

2   hospitals need this.

3   Now, I don't know what the costs associated

4   with doing that are. But my guess is that they're

5   minimal compared to the impact on improving patient

6   safety.

7   MR. ZOPH: I guess my follow-up on that would

8   be that, again, we talked about the repackaging issue.

9   If you look at what's the right thing to do, the time

10 to do this is the time of manufacture that's the

11 highest quality and safest place to do it.

12   And secondly, there are a lot of costs of

13 adoption, which we've talked about. So if the

14 manufacturing industry embraces this, the cost of

15 embracing is then the unit of use at the hospital level

16 employing the technology, training the people and so

17 on.

18   So there are costs, but I think there are

19 costs to the complete system. But again, the right

20 point to do this with the highest quality, I believe,

21 is at the point of manufacturer.

22   MS. DOTZEL: And then my second question is

1 that there's been a lot of discussion about three data

2 elements in the barcode, the NDC number, the expiration

3 date, and the lot number. Are there any other data

4 elements that we should be considering?

5   DR. COMBES: No. I don't think so. And this

6 is why I have a little concern about the expiration

7 date and the lot number, that there might be another

8 way to get at it.

9   I think if you look at a barcode as really not

10 a very intelligent item -- it's really a pointing

11 device, a pointing device to a database -- you really

12 don't have to have too much in the barcode as long as

13 you have the databases to back it up.

14   Now, what we're asking you to do is make that

15 barcode a little bit more intelligent for this labeling

16 purpose by having the NDC number in it, and then beyond

17 that, to get the expiration date and the lot number.

18 But there are -- other elements that you may need will

19 come when we again integrate our systems in able to

20 point that barcode at these other databases.

21   So I don't think the FDA needs to get that

22 into the barcode to make it smarter. We should be able

1 to do that by, again, working with industry to get some

2 standards about how we can point that barcode to all

3 these different databases we have.

4 The problem is as you start putting too much

5 information in the barcode, then the real estate on the

6 label gets taken up by the barcode. Even with some of

7 the reduced symbologies, you're not going to get the

8 information in there.

9 So I think where we are, to get the three

10 items in it, would be very, very good. If we can start

11 with the NDC number, that would at least get us -- get

12 the ball rolling.

13 FDA PANELIST: One question I have that the

14 panel can comment, and perhaps some of the speakers

15 later in the day that are going to address device

16 issues. But often, with medical devices, the same

17 labeling is used in multiple countries.

18 And part of my question is, first, if you have

19 any comments on what's happening in Europe or other

20 kinds of systems with these kinds of technologies. But

21 the other pressure that comes up in the device area in

22 using -- moving to the increased use of symbols, not

1   just barcodes but other types of symbols, is to

2   actually decrease the amount of language on the label

3   and develop standardized meaning for symbols, like

4   symbols for expiration date and other types of symbols,

5   in part because of the European Union requirement to

6   have information in all 17 languages of the European

7   Union on the label. And for small products, that gets

8   to be quite challenging.

9   So it's kind of a general question. But the

10   question is, do you have some comments about, you know,

11   where you see the future of getting standardized

12   elements? And if you have any comments on the

13   international scene?

14   MR. THOMPSON: I'll just make an indirect

15   comment. We've talked about staggered implementation

16   of things. I would suggest hat the FDA stay very

17   focused on writing a workable regulation to provide

18   barcodes on all pharmaceutical product packages down to

19   the unit dose level.

20   I think it would be fantastic one day if we

21   had devices barcoded. But I think the greatest impact,

22   the greatest area of impact, on improving patient

1   safety is on the pharmaceutical product package.

2   I can't speak with any expertise about any of

3   the issues that are going on in Europe with devices. I

4   mean, I've worked with device failures in healthcare.

5   But, you know, by and large, let's stay focused on

6   getting barcodes on pharmaceutical product packaging.

7   FDA PANELIST: Actually, my question extended

8   to pharmaceuticals as well. To your knowledge, does

9   Europe use barcoding or other kinds of systems in their

10   pharmaceutical systems?

11   DR. COMBES: It's my understanding that they

12   do not use the NDC, which would be a problem. They're

13   using universal product number, and that would be a

14   whole nother issue that I think we would open up.

15   I think we have -- the NDC is something that

16   we have. It's pretty pure. And I think, again, it

17   would be very helpful because hospitals use it. Others

18   use it to recognize drugs. It's used for reimbursement

19   purposes.

20   So I think that's the major difference between

21   the European system and our system.

22   FDA PANELIST: At the practical level, what it

1 would get down to would also be things like importation

2 rules, whether drugs could be imported if they didn't

3 have barcodes, NDCs, things like that.

4   MS. DOTZEL: I think now I'd like to give

5 people in the audience an opportunity to ask any

6 questions of our panel members. We have microphones in

7 each of the aisles. And so if anyone has anything,

8 please step forward to the microphones.

9   AUDIENCE MEMBER: Can we make a comment or ask

10 a question? Either?

11   MS. DOTZEL: Questions for the panel is what

12 we're looking for now, please.

13   AUDIENCE MEMBER: Okay.

14   (Laughter)

15   MS. DOTZEL: And if you could identify

16 yourself as you come to the mike, that would be great.

17   MR. BRODO: Hello. A question. I'd like to

18 just explore with the panel for a moment the

19 intersection between this proposed regulation and the

20 Prescription Drug Marketing Act; specifically, comments

21 around the tracking of promotional drug samples and the

22 use of barcodes on those packages.

1   Oh, I am sorry. My name is Robert Brodo. I

2   am sorry. LScan Technologies.

3   MS. CIPRIANO: Was your question basically,

4   should they be barcoded as well?

5   MR. BRODO: Yes. Is it your recommendation,

6   is it part of your proposal, to make sure that

7   barcoding is extended to all drugs, including not only

8   in use in the hospital in use to patients, but also

9   promotional drug samples? And there's implication as

10 that perhaps transcends the Prescription Drug Marketing

11 Act.

12   MS. CIPRIANO: My simple answer would be yes,

13 for a lot of reasons, again, because the need to

14 control the use of samples and track who they've been

15 given to and what happens is probably even more

16 difficult in an outpatient setting.

17   And so, again, it enables us to be able to

18 track what patient, you know, got the medication, and

19 be able to then carefully -- be able to have the data,

20 just as if you were dispensing another prescription.

21   DR. COMBES: My answer would be yes. But I

22 think in some respects, we're making the next leap.

1 What we're asking the FDA to do here is to put the

2 barcode on the label of all drugs, over-the-counter

3 drugs -- we're asking over-the-counter drugs,

4 prescription drugs. So it wouldn't matter if it was a

5 sample. It wouldn't matter -- every unit dose would

6 have a barcode on it, or any unit packaging would have

7 a barcode on it.

8   How that's used is going to be a whole

9 different issue. And I don't think we're asking the

10 FDA to tell us how to use it. We're asking them to

11 give us the tool so we can use it.

12   And so we may be looking to some point in the

13 future where physicians will scan the samples they hand

14 out in their office and keep a record of it in their

15 hopefully electronic medical record in their office

16 someday. I mean, that's -- who knows. I won't be

17 alive to see that.

18   But again, that -- but you can't do that

19 unless you have the barcode on there. So we're asking

20 them to take the first step on that.

21   MR. BRODO: Thank you.

22   MR. RITTENBURG: I'm Jim Rittenburg with

1   Biocode. And I wanted to ask the panel if they've

2   considered using the barcode to also be a tool for

3   helping to prevent diversion and counterfeiting, or

4   diverted and counterfeited products from entering into

5   the distribution chain by individually license plating

6   every item through the barcode that's put onto that

7   item.

8   MR. THOMPSON: I don't know if I can answer

9   your question perfectly. But I think a lot of that

10   would be taken care of if the pharmaceutical

11   manufacturer producing the product was also doing all

12   the packaging, and including the data elements on the

13   barcode.

14   I can't really go much deeper into that than

15   that but to say yes, I think that would be useful for

16   that purpose.

17   MR. RITTENBURG: Yes. Because the only

18   additional comment I'd make is with the recent cases of

19   counterfeiting that have occurred, in many cases it's

20   been due to labels being copied, and any information on

21   that would also be copied.

22   So if a barcode only had an NDC number or lot

1   number, that could be produced en masse and copied,

2   whereas if it was individually identified for every

3   item, it would be much more difficult for somebody to

4   just copy labels off and shove it into the distribution

5   chain.

6   MR. MAYBERRY: My name is Peter Mayberry. I'm

7   with the Health Care Compliance Packaging Council. A

8   follow-up on the European question and the question

9   about, you know, other countries specific to

10 pharmaceuticals.

11   Kasey, you made the dichotomy between unit of

12 use and unit dose. In your experience, do many other

13 countries -- are you aware of other countries which do

14 dispense in unit dose as opposed to bulk distribution,

15 which we rely on in this country?

16   MR. THOMPSON: That's a good question, and I

17 don't have any science to back this up. But I was on a

18 recent vacation to Vietnam, Singapore, and Tokyo, and

19 just walked through community pharmacies in those

20 countries, they primarily dispense product in unit dose

21 and unit of use packaging. That was just an

22 observational method I used. But it seemed very common

1   in Asia.

2   MR. MAYBERRY: That also relates back to the

3   cost. I mean, if they can afford to do it over there,

4   do you have any speculation on why we can't afford to

5   do it here?

6   (Laughter)

7   DR. COMBES: Well, unit dosing for most

8   pharmaceutical companies is not a big part of their --

9   for hospitals, at least, a big part of their product

10   line. I mean, they're not dispensing a whole lot of

11   unit doses.

12   However, over-the-counters are almost always

13   in unit doses. So obviously, it makes sense in an

14   over-the-counter product that you're dispensing -- any

15   time you get a cold preparation, it's always in the

16   unit dose blister pack.

17   So I'm not sure why the problem is, except

18   that it hasn't been a big part of what they've been

19   selling to hospitals in the past, and putting another

20   burden on -- may have them shut down those lines, which

21   we think are very, very important for patient safety

22   reasons.

1   MR. THOMPSON: And that was an excellent point

2 you made, and I would highly encourage you to ask the

3 pharmaceutical insurance company that question this

4 afternoon.

5   MS. SHAW: Hi. My question is for

6 Dr. Cranston. And --

7   MS. DOTZEL: Could you provide your name,

8 please?

9   MS. SHAW: I'm sorry. It's Sherry Shaw, from

10 Aventis Pasteur. And just specifically somewhat

11 related to the sampling issue, but with vaccines,

12 almost all of the vaccines are administered within the

13 office setting as opposed to a hospital setting. And

14 in order for such a system to be effective, it really

15 would require physicians' adoption of the technology at

16 the office level.

17   What would you foresee uptake at the physician

18 level to be with regard to that type of technology?

19   DR. CRANSTON: Frankly, I don't have a clue.

20 I really don't know. I think that based on the major

21 discussion we're having here today and the slow uptake

22 by hospitals because of the lack of barcoding of the

1 products that are available commercially, you know, my

2 suspicion would be that it would be relatively slow.

3 But, you know, as we talk about computerized

4 order entry and the likelihood that that's going to

5 become mainstream in the not-too-distant future, and as

6 the cost of scanning devices, you know, are very low,

7 you know, I think that that will happen. But at this

8 time, I don't think it's been thought about.

9 MS. SHAW: Thank you.

10 MR. GALLAGHER: My name is Derek Gallagher.

11 I'm with Aventis Pharmaceuticals.

12 Is there any data that shows either the number

13 or the impact of medication errors due to dispensing of

14 expired product or recalled lots, as opposed to wrong

15 product or wrong dose?

16 MR. THOMPSON: None that I'm immediately aware

17 of, but that would certainly be something I would be

18 happy to look up and verify and get you the information

19 if it's available.

20 MR. GALLAGHER: Thank you.

21 MS. TABORSKY: My name is Jeanne Taborsky and

22 I work for SciRegs Consulting. We represent a number

1 of different kind of drug companies. I have two

2 different comments.

3   One is that while we've been talking about all

4 these products, one of the products where there have

5 been some MedWatch reports are nebules. These are the

6 little plastic devices that have drug, and they're used

7 in nebulizers.

8   And FDA currently does not allow us to label

9 those directly. And they're currently packaged in

10 pouches, and then the pharmacist will -- at the

11 hospital scene will take them out of the pouches and

12 sometimes put them in bins. And there have been some

13 instances where the pharmacists have actually had

14 problems where they have mixed them up in bins.

15   One thing, we're going to need agency help in

16 trying to find a way to label nebules where we can't

17 even put a label on them. Because I don't know of any

18 way to barcode something without a label. So that's

19 one thing to consider.

20   The other is, on OTC products where we have --

21 we're trying to put a lot of information on small

22 blisters already. I don't see where the person in

their home is going to gain advantage of having a

barcode on that small blister for an OTC product. And

a lot of these people are getting older, and as we're

getting older our eyes are having more trouble reading

small print. And so it's just something else to

consider, as to how we're going to put a barcode on

each individual blister of material.

Any comments?

DR. COMBES: The only comment I would make is

that we use OTC products all the time in hospitals.

And if we have an integrated system where we're doing

bedside scanning, including prescriptive medications as

well as over-the-counters, we would certainly like to

have the advantage of scanning the over-the-counters as

well.

And again, I don't know that you can predict

what the future is. And I agree the real estate on an

OTC blister pack may not be all that large. But the

symbologies are getting smaller, and there are kind of

unique ways.

I was at the recent packaging conference, and

everybody had blisters with lots of information on them

1   and barcodes on them. And I think we need to look at

2   it because you don't know where the technology is

3   going. And it may be at home people will be using more

4   of these kinds of devices in the future.

5   MS. TABORSKY: Thank you.

6   MR. BILLS: Hi. My name is Ed Bills, from

7   Hill-Rom. And my question is for Dr. Feigal.

8   We've been talking about the label and

9   concentrating a lot on the label. But it looks to me

10   like we're introducing a new medical device here. And

11   what do you see the product clearance process for the

12   barcoding system to be, and how long will that take to

13   get in place?

14   DR. FEIGAL: The thought occurred to me as

15   well.

16   (Laughter)

17   But there are a number of hospital information

18   systems that we have chosen not to regulate. Some of

19   them are actually Class I exempt. But we would look at

20   these and have to see where they fit into the

21   framework.

22   But in general, if you look at most

1   laboratories' information systems, things like that, we

2   historically have not chosen to regulate those.

3   MR. RACK: Bob Rack, RDG Barcode America.

4   This is particularly directed to Dr. Combes.

5   You've indicated that NDC is a first step.

6   Okay? And you can do that with your existing scanners.

7   It's also been indicated here that only 1.1 percent of

8   hospitals are using any scanning technology. You've

9   indicated that you want to stay with existing scanning

10 technology, even though you also indicated that over

11 four to five years, these existing scanners will cycle

12 out.

13   At the same time, you've indicated that you'd

14 like to see the expiry date and lot code put on there,

15 and to accomplish that, you need to go to either RSS

16 codes or data matrix codes, particularly on your small

17 packages. At the same time, you've indicated your

18 resistance to data matrix multiple times. And you're

19 trying to do two things that they're exclusive to one

20 another.

21   And my other point, you've made reference

22 multiple times to the extreme cost of data matrix

1   reading devices. They can be had for under $500.

2   DR. COMBES: What I was saying to you was that

3   we have made -- maybe only 1 percent of hospitals are

4   using scanning at the bedside. But we're using

5   scanning all throughout the hospital. We're using

6   scanning for inventory control. We're using scanning

7   for laboratory specimen identification. We have

8   scanners available in the institution.

9   My understanding -- and I may be wrong on

10   this, and we've spent some time trying to understand

11   it -- is that an RSS code can be read by the current

12   generation of scanners that we have in the hospitals

13   that are not optical scanners, and that what I was

14   saying is that the older scanners that are not current

15   generation will be cycled out, will be replaced, by the

16   current generation, which can read RSS, can read

17   composite barcodes.

18   So what I'm trying to say to you is we don't

19   think we should move to the next order of magnitude of

20   scanners, replacing the scanners we currently have in

21   the institution. And some of them are current

22   generation scanners that we're using in various

different departments within the hospitals.

We are not scanning at the bedside precisely because we don't have the barcode on the medication, and that's what we're asking for.

MR. RACK: But when you're talking about inventory control, you can do that with current existing technology. When you're going to small packages, you have to go to the next step. When you talk about reprogramming existing scanners that you have, okay, that can be done to read certain subsets of RSS. But they may not be the subsets that can fit on this information that's required.

If we're only doing the NDC number, you're right. But if we're going to do the expiry date and lot code, it's not right.

DR. COMBES: That's why I said the expiration date and the lot number needs to be phased in because there are technical issues there. And I've heard all sides of this argument, and I don't think we're going to be able to resolve it today. It's going to take some time in sitting down with people who know a lot more about this than I do to figure out how you can do

1   this.

2   But my understanding, that there's a

3   possibility it can be done using the current generation

4   of scanners that we have in the hospitals. Again, I

5   think there's going to be a lot of technical work that

6   has to be done around this issue. I certainly don't

7   have the expertise to answer it today, but I do think

8   people do have it, and I think if we take a measured

9   approach, we'll get to that point.

10   Our concern is just, let's get something on

11   the label that we can start to work with. We don't

12   scan at the bedside because there's nothing to scan

13   right now.

14   MR. RACK: Okay. I guess my point is, if you

15   stay at NDC number, you're okay. Thank you.

16   MR. GROSS: Hello. My name is Michael Gross,

17   from Aventis Behring.

18   I'd like to ask the healthcare provider panel

19   what thoughts they have about how this is going to

20   impact the use of diluents that are used to

21   reconstitute dry products for injection. What

22   complications are going to be derived from this, the

1   labeling of those products?

2   MR. THOMPSON: Expand a little bit. I'm not

3   sure I understand your question. Now, we would support

4   diluents are pharmaceutical products also being

5   barcoded.

6   MR. GROSS: I believe that not all of them

7   contain NDC numbers. Some of them are sort of

8   customized diluents for particular products that really

9   go with the product. Sometimes, as I understand it, in

10   practice, the diluent can get separated from the actual

11   drug that it's used for, I think, in practice. You

12   might know more about that than I do, but this is what

13   I hear.

14   So I think there's some complications around

15   diluents. And I guess I'm asking if you've thought

16   this through and how this might work.

17   MR. THOMPSON: Not in any great detail related

18   to diluents specifically. However, one thing that we

19   have recognized as hospital/health system pharmacists

20   is that even if we get manufacturers producing all

21   products in unit dose packages and making those

22   available to hospitals, we're still going to have to do

1   some repackaging within the pharmacy department and

2   some barcoding at the pharmacy department level.

3   We heard about pediatric institutions and

4   children's hospitals and the specialized dosage forms

5   there. So the capability to barcode at the hospital

6   level is still going to have to be there for some

7   products.

8   And I don't know if I'm addressing diluents in

9   that or there's some other technical issues or

10 regulatory issues associated with that. Perhaps the

11 FDA can help answer that one.

12   MS. CIPRIANO: Let me just comment on your

13 statement that the diluent gets separated from the

14 medication.

15   MR. GROSS: That's what I understand that

16 happens.

17   MS. CIPRIANO: Well, I would hope that's

18 really not happening, I mean, because the final

19 preparation, all of those contents should accompany it

20 through all of the system checks that are done before

21 that medication would be released.

22   So that part of the medication cycle would

1 really need to be examined if in fact it was separated

2 before all of the final checks. I mean, again, every

3 institution has its system. But I would be surprised

4 if that is happening to any great extent.

5   MS. DOTZEL: Before you ask your question, let

6 me just ask that everybody who's standing up to ask a

7 question, we'll go through those questions, and then

8 we'll probably break after that.

9   MS. ALLINSON: Hi. I'm Jen Allinson from

10 Procter & Gamble Pharmaceuticals.

11   I have a question about whether or not the

12 rule would be extended to repackagers.

13   FDA PANELIST: We haven't made any final

14 decisions about the rule. We're here to get input

15 today. Do you have something you want to say about

16 that?

17   MS. ALLINSON: Well, I guess what I want to

18 say is mostly what these folks are using are items that

19 are coming from repackagers. So if that rule is not

20 extended to those folks, then there is a great

21 possibility that you're still going to be dealing with

22 the same issues.

1   DR. COMBES: We would like to see it extended

2   to repackagers. We'd like to see a common standard

3   that everybody uses so that there is no confusion about

4   what scanning device to use or where to use it or what

5   information is in there, so certainly any time a

6   pharmaceutical comes into the hospital, either

7   repackaged or packaged originally from the

8   manufacturer, there's a barcode on it that we could

9   read at the bedside.

10   MS. ALLINSON: Thank you. Second question:

11   Regarding your comments about not wanting to see data

12   matrix because of barcode scanners, et cetera, that

13   could potentially increase the costs to all the

14   manufacturers because we would potentially have to go

15   to one standard now.

16   And then if we want to add lot number and

17   expiration date later and have to go to, you know, data

18   matrix, now we're making a whole second change in terms

19   of all of our labels, all of our, you know, printing

20   capabilities, et cetera, et cetera. So you may be

21   actually creating a barrier for the pharmaceutical

22   industry to provide the data that you need.

1   DR. COMBES: I recognize that. But there are

2   some manufacturers right now that will put a barcode on

3   with the NDC and then add the composite afterwards in

4   the last step of the manufacturing process so they can

5   get into the lot number and expiration date because you

6   don't have that information until you're coming off the

7   line, basically.

8   And so if the technology is there -- and this

9   is why I say we think it needs to be phased in -- it

10   may be possible to have it linear coded, and then have

11   a barcode either adjacent to it in the composite form.

12   MS. ALLINSON: You're right. That is a

13   possibility. But it is something that's even less

14   developed and more uncertain for high-speed lines. So

15   I would just keep that in --

16   DR. COMBES: And I understand that. And

17   again, that's why -- but if we wait till we get it

18   perfect and get the right scanners to get all three

19   elements on, we might be sitting around for the next

20   several years being right where we are today.

21   MR. HANCOCK: Ed Hancock, American Health

22   Packaging.

1   What we're talking here today is an issue

2   that's significant enough for regulation, for federal

3   regulation. And there's a lot of discussion about what

4   is critical and what is nice to have, questions focused

5   around that.

6   I think Dr. Crawford set the scene this

7   morning when he spoke of 100,000 deaths annually

8   through -- and many through medication administration

9   errors. So it's critical that we figure out this,

10   what's critical and what's nice to have.

11   My question to the panel, to each and all of

12   the panel, and I think it can be answered in a yes or

13   no: Does the content of the NDC, which defines the

14   medication, manufacturer, and strength, coded on the

15   package provide sufficient information by itself to

16   address the five rights -- right patient, right

17   medication, right dose, right time, right route?

18   MR. THOMPSON: The answer is yes. But that's

19   one part of the medication use process which is an

20   extremely complex process. So also the ability of

21   having lot number and expiration date for product

22   tracking, recall, and identifying whether a product is

1 in date or out of date would be very useful.

2   I mean, you mentioned the 100,000 deaths

3 associated with medical errors. A subset of that in

4 the IOM was 7,000 related to medication errors. Do we

5 have to wait until an expired product caused a patient

6 harm? Do we have to wait until we have a product

7 recall that we really need to be able to track who got

8 what and when?

9   I completely agree, the NDC has the necessary

10 data elements. It is the primary element within the

11 code that will be the most useful at the bedside for

12 preventing administration errors. But let's not

13 minimize the complexity of the medication use process

14 and, you know, just put these things on the back burner

15 and forget about them five years from now.

16   MR. HANCOCK: I understand the possibilities

17 are enormous if we expand.

18   Others?

19   DR. COMBES: I think our position, from the

20 American Hospital Association, is pretty clear. I

21 mean, we think we can get a lot out of having the NDC

22 number on it.

When you say, you know, does it guarantee the five rights, well, if you're giving an expired drug or a recalled drug to somebody, then you're not giving the right drug any more. So again, you know, nice to have the ability to get that information.

Again, off the top of my head, I wonder if there's a way to do that by using the barcode as a pointing device since the lot number and expiration date -- and I may be wrong about this -- but is generally in the shelf-keeping unit.

And if there's a way to link the dose that you're delivering back to the shelf-keeping unit in your database, you may be able then to pick up the lot number and expiration date.

There are different ways to look at this, and I think we have to explore that. But it is very clear that tomorrow, if we had the will, we could get that NDC number on the unit of use and have it barcoded.

MS. ESTHER: I'm Sarah Esther. I'm a pharmacy student from Purdue University.

And I was wondering if the panel had any comments on the implication of barcode labeling

1 requirements on pharmacists' jobs, and if this might

2 eventually lead to the elimination of pharmacists in

3 some practice sections and greater responsibilities for

4 technicians who might now have the final check.

5   MR. THOMPSON: Well, I'm the pharmacist on the

6 panel, and I'm fairly confident that this will not

7 eliminate the need for pharmacists as the experts in

8 the medication use process and the use of medications.

9 Very good question.

10   But this is another layer of protection for

11 the patient. And, you know, that's the way we need to

12 look at it. You know, I mean, all of us as healthcare

13 professionals, if we could develop systems that

14 protected patients and provided total failsafes and we

15 were all out of jobs, we all become obsolete and out of

16 a job, then we've done our job.

17   So we're not going to get to that point.

18 Systems are complex, and I think you have a long career

19 ahead of you.

20   (Laughter)

21   DR. COMBES: Also, a little reassurance from

22 the hospitals' perspective. One of the things that's

1 very clear in the patient safety movement, and does

2 ensure safety of the medication system, is use of the

3 clinical pharmacist as part of the care team.

4 The more we can free the pharmacist up from

5 this routine of checking and counter-checking and

6 counting and doing everything else, and getting them

7 involved in the care team, the better off our patients

8 are.

9 The amount and complexity of pharmaceuticals

10 we use in healthcare is amazing, and no physician, no

11 nurse, can do that on their own. And the more we

12 employ clinical pharmacists to round with us, to help

13 us tailor drug regimens, and to work as part of the

14 team, the better off everybody will be. So I wouldn't

15 worry about it, either.

16 MR. MURRAY: Good morning. My name is John

17 Murray. I'm in the Office of Compliance for the Center

18 for Devices.

19 My question is for the industry panel. Do you

20 envision that this barcode regulation will address the

21 validation, the design control, and the overall quality

22 of systems? And if it's not going to be in this

1   regulation, what is your recommendation about how we

2   approach that problem to ensure that these systems

3   actually work to protect public health?

4   (No response.)

5   I have a part B question for the lawyers.

6   (Laughter)

7   My part B question is, how do you envision

8   that this barcode rule will impact on legal liability?

9   Currently now I guess it's, you know, a practice of

10 medicine, that whole legal liability history. Will now

11 we shift the big error blame to the IT system, take the

12 human out of the loop?

13   And then who gets -- who is liable? Is it the

14 hospital? The barcode maker? The label maker? I

15 mean, I'm just wondering how this could shift the scale

16 of justice.

17   MR. THOMPSON: Now, I'm not an attorney, but

18 we're not talking about taking the human out of the

19 loop here. We're talking about providing humans with

20 another layer of protection for patients as part of the

21 process.

22   So, you know, this isn't a way to take the

1 human out of the loop. So we'll let an attorney answer

2 the question related to legal liability, but --

3   MS. CIPRIANO: Let me just add one other

4 issue, though, that hospitals are facing. The more we

5 move to technology, and I'll just use robotics as an

6 example, we are seeing limits on liability from the

7 manufacturers.

8   And so whether it's the repackagers or whether

9 it's the dispensing manufacturers, I think there's

10 growing tug and pull in terms of how contracts are

11 written and where the liability is placed.

12   And so I think it is an issue that we have to

13 pay some serious consideration to because, you know,

14 institutions are willing to buy into technology, and

15 even if we believe that the systems are 98 to

16 99 percent accurate, there is certainly that concern

17 about risk when you are buying a system in order to

18 reduce your liability to begin with for errors.

19   So I think it's an unanswered question and an

20 important one that you raise.

21   DR. COMBES: I think the other challenge for

22 hospitals is that having the barcode on a label will

1   probably create some liability, and probably in a good

2   sense that there'll be an expectation that it's used.

3   And when it's not used and patients suffer from a

4   medication error, it will be pointed out to us quite

5   clearly. You have this capability to do something.

6   Why don't you do it?

7   And I think that's really going to be the

8   pressure to make the industry move forward in using

9   information technology much more judiciously than we

10   have in the past, and for better patient outcomes.

11   MS. DOTZEL: Well, that concludes our morning

12   session. I'd like to thank the panel for getting us

13   off to a good start today. I think the discussion this

14   morning has been very productive, and I think it's

15   gotten everybody thinking about the issues we want to

16   continue to talk about this afternoon.

17   There is a cafeteria upstairs on the main

18   floor. You may have seen it as you came into the

19   building this morning. They're expecting us, so we'll

20   break now. We are going to reconvene at 12:15.

21   (Whereupon, at 11:20 a.m., a luncheon recess

22   was taken.)

1   A F T E R N O O N   S E S S I O N

2   12:18 p.m.

3   MS. DOTZEL: We're going to start in a minute.

4   Why don't the members of our next panel come on up and

5   take your seats while everybody else is getting seated.

6   Okay. Why don't we get started. Before I

7   introduce our next panel, I'm going to walk through the

8   government panel again. We've had a few changes for

9   this afternoon's session, and I just want to make sure

10   that everybody is acquainted with who's up here.

11   Starting with Dr. Steven Galson. He's the

12   deputy center director in our Center for Drugs. Seated

13   next to Dr. Galson is Dr. David Feigal, who is the

14   center director in our Center for Devices. Seated next

15   to Dr. Feigal, we have Nancy Gieser, who is the acting

16   director on our economics staff in the Office of the

17   Commissioner.

18   And then Diane Maloney, who is the associate

19   director for policy in the Center for Biologics. And

20   sitting next to Diane, we have Peter Beckerman from our

21   Office of Chief Counsel.

22   And our panel this afternoon is the industry

1   panel. We have representatives from the different

2   trade groups, and I will call you up individually.

3   I'll walk through the panel so that everybody knows

4   who's up here, and also so I can make sure I know

5   everybody who's up here.

6   We have Richard Johnson here representing

7   PhRMA. Steve Bende from the Generic Pharmaceutical

8   Association. We have Bill Soller from the Consumer

9   Healthcare Products Association. Kay Gregory is here

10   on behalf of the American Association of Blood Banks,

11   the American Blood Centers, and the American Red Cross.

12   We have Mary Grealey, here from the Healthcare

13   Leadership Coalition. And Tess Cammack -- am I saying

14   that correctly? -- representing AdvaMed.

15   And with that, we'll get started. We'll start

16   with Dr. Johnson from PhRMA.

17   DR. JOHNSON: Thank you for the opportunity.

18   Can everybody hear me? Okay? Hopefully everybody had

19   a good lunch and has come back energized to hear more

20   about barcodes this afternoon. I'm very pleased to be

21   able to offer the PhRMA statement regarding barcode

22   label requirements for human drug and biologic

1   products.

2   PhRMA continues to be supportive of efforts to

3   utilize standardized barcodes down to the unit of use

4   level on drug and biologic products as part of an

5   initiative to reduce medication errors. Current

6   printing and scanning technology allows for the

7   application and reading of a barcode on the label for

8   all but the smallest primary containers. Here are some

9   examples.

10   PhRMA encourages the use of a standard barcode

11   and data structure for encoding the NDC number in these

12   applications. The NDC number is a unique identifier

13   for the manufacturer or distributor, the drug

14   formulation, and package size and type.

15   In addition to the currently used UPC code and

16   Code 128 symbologies, which you can see here, PhRMA

17   also endorses the reduced space symbology and the 2D

18   code data matrix. And for those of you that may not be

19   so familiar, maybe it's helpful to see what they look

20   like. This is another example. This is a Code 128 on

21   a different type of package.

22   Based upon the current state-of-the-art

1   technology available for incorporating barcodes on

2   small container labels, it may be necessary to amend

3   current FDA text requirements so that certain human-

4   readable information now required to be on all primary

5   drug and biologic container labels be exempted.

6   This would provide sufficient space to print a

7   high-quality machine-readable barcode and more

8   prominent human-readable text to help reduce medication

9   errors. And I thought this was a good illustration of

10   how small some of these container labels that we're

11   dealing with can be.

12   If there were agreement on the above

13   conditions, it would be possible for pharmaceutical

14   manufacturers to extend the use of machine-readable

15   barcodes on container labels where there's available

16   space, and have those barcodes on such container labels

17   within two to three years.

18   For container labels where the necessary space

19   is not readily available, the feasibility of

20   incorporating the NDC number into a machine-readable

21   barcode and the timing for its implementation would

22   require further discussion with the FDA regarding

1   requirements for handling exemptions and supplements

2   for label changes.

3   The present technology is limited in its

4   ability to support the application of machine-readable

5   barcodes incorporating additional information beyond

6   that contained in the NDC number, such as product lot

7   number and expiration date. These are variable

8   information that would have to be applied lot to lot.

9   And you can see some of the wide variety of

10   pharmaceutical packages that we deal with.

11   The material benefit of a barcoded lot number

12   and expiration date to achieve a reduction in

13   medication errors warrants further discussion among

14   stakeholders.

15   As a recent paper from NCCMERP cites, further

16   research is needed to quantify the safety and cost-

17   effectiveness of barcoding in the medication use

18   process, and should be undertaken before their

19   universal incorporation into these processes. The use

20   of barcoding technology as a mechanism to improve

21   medication safety should be implemented incrementally

22   with careful planning, and given thoughtful

1   deliberation for cost, cultural, and implementation

2   issues.

3   PhRMA is prepared to convene a group of

4   interested stakeholders to do this kind of needs

5   assessment, and looks forward to the opportunity to

6   work with the agency and other stakeholders in efforts

7   to improve patient safety. Thank you.

8   MS. DOTZEL: Thank you, Dr. Johnson.

9   Next we have Dr. Steven Bende, who is here on

10 behalf of the Generic Pharmaceutical Association.

11   DR. BENDE: Good afternoon. On behalf of the

12 Generic Pharmaceutical Association, I'd like to thank

13 Secretary Thompson and the FDA for their efforts to

14 reduce medication errors, and for providing an

15 opportunity for industry comment on barcode labeling of

16 human drugs and biologics.

17   GPHA represents 98 percent of the generic drug

18 manufacturers whose drugs are dispensed for 45 percent

19 of all prescriptions written in the United States, and

20 representing less than 10 percent of total drug

21 expenditures.

22   GPHA is now the united voice of the generic

1   drug industry. We are completely committed to patient

2   health and safety, and strongly support any measure in

3   all areas that improve these. Indeed, the foundation

4   of our industry relies on the safety and effectiveness

5   of affordable pharmaceuticals to provide increased

6   access to therapeutically equivalent prescription

7   medications for all patients.

8   Consistent with this commitment to quality and

9   safety, GPHA firmly supports the comprehensive use of

10   standardized barcode labeling on human drugs and

11   biologics. We also support the use of associated

12   standardized data formats to aid in the reduction of

13   medication errors.

14   Now, clearly there are some hurdles to

15   overcome, and we've heard about a lot of those this

16   morning, including space limitations of smaller drug

17   packages, current regulations on label text

18   specifications, and the state of technology to actually

19   apply barcoding to packaging online in high enough

20   quality and high enough speed to insure readability.

21   Other issues include what information we've

22   been hearing a lot about, lots and expiration date

1 numbers, and which of the various technologies we

2 should standardize on.

3   At this time, we will not be making a

4 recommendation for technologies to support or what

5 information should be on there -- should be contained

6 in any code. However, we do support -- from hearing

7 from our health system colleagues this morning, we do

8 support NDC number, lot number, and expiration date.

9 And how many of those and which of those are included

10 immediately needs to be debated.

11   To that end, we recommend formation of a task

12 force to swiftly investigate solutions to these issues

13 to aid the agency in developing new barcode regulations

14 that might result in decreased medication errors. Some

15 of the participants of this task force should include

16 end users of the technology, pharmacists, drug

17 manufacturers, FDA, and especially the technology

18 companies who make the technologies behind barcode

19 labeling and the scanners.

20   We stand ready to participate in such a task

21 force, and we extend an offer to assist in its

22 formation and operation. And thanks for the chance to

1   make these comments.

2   MS. DOTZEL: Thank you, Dr. Bende.

3   Up next we have Dr. William Soller, who is

4   here representing the Consumer Healthcare Products

5   Association.

6   DR. SOLLER: Good afternoon. I'm Dr. Bill

7   Soller. I'm senior vice president and director of

8   science and technology for the Consumer Healthcare

9   Products Association, CHPA. We represent manufacturers

10   and distributors of nonprescription medicines and

11   dietary supplements.

12   CHPA supports efforts to reduce medication

13   errors, including those that encompass errors in

14   information acquisition by consumers, who are the

15   principal end users of self-care products, as well as

16   by those in the professional setting that also might be

17   using OTCs.

18   Potential market-based solutions and the

19   ability to leverage existing systems are critical to

20   our industry, and I have three general areas of

21   comment. First, in the consumer self-care setting,

22   drug facts labeling is a means designed to address

1   medication errors. Barcoding to prevent medication

2   errors would not be of value in the self-care setting.

3   OTC manufacturers and FDA have been mutually

4   concerned about optimizing safe and effective use of

5   OTCs through even better labeling, including ways to

6   minimize medication errors in the self-care setting.

7   Working with other groups, including CHPA, FDA

8   developed the Drug Facts Final Rule for improving the

9   content and format of all OTC labels for outer

10 packaging to make essential information on use and

11 selection easy to access and comprehend.

12   This regulation dictates the format, order,

13 print size, content of wording which the lay consumer

14 will receive when they obtain an OTC drug, and requires

15 the active ingredients section to appear first on all

16 information in a special box entitled "Drug Facts,"

17 which also contains directions of use, warnings,

18 storage information, and lot number and expiration date

19 are required by separate regulation.

20   The new drug facts labeling is an important

21 step to reduce potential medication errors in the self-

22 care setting. And in the development of the drug facts

1   box, consideration was given to how consumers use

2   nonprescription drug products in the OTC setting, which

3   is quite different than OTC utilization in the

4   professional setting.

5   In the self-care setting, this encompasses

6   self-selection by consumers and represents the vast

7   majority of self-use of nonprescription medicines.

8   Access and veterans are key drivers to purchase

9   decisions, and reliance on the consumer reading the OTC

10 label is the principal stratagem for self-care with

11 OTCs. We want and we encourage consumers to read the

12 label, to understand their medication, and to dialogue

13 when necessary with health professionals.

14   It's unlikely that the use of barcodes by

15 consumers in the non-institutional self-care setting is

16 reasonably feasible or preferred over the human-

17 readable printed label to prevent medication errors.

18 Scanners are needed to read barcodes.

19   Consumers do not have handheld scanners linked

20 to their personnel medication records. Further, they

21 most likely don't have the need nor the desire for such

22 access, given their state of health, current

1   medications, and cost and upkeep of what might be

2   envisioned as a futuristic personal scanning system for

3   all consumers.

4   My second general point is that the universal

5   product code, the UPC on OTCs, is an efficient and

6   effective means to track retail distribution and sales.

7   Currently, all OTC products intended for retail sale

8   bear a barcode, the UPC on the outer container.

9   The UPC is a unidimensional barcode that can

10   be read at high speeds at the checkout counter. It is

11   the symbolic representation of a number, like a license

12   plate, which is assigned by the manufacturer for

13   tracking each SKU or shelf-keeping unit through its

14   distribution and sales network.

15   Since the UPC is a number, it is simply a link

16   to a different electronic-based archival system within

17   distribution centers and retail stores. The vast

18   majority of the 750,000 OTC retail locations use the

19   UPC to track some 150,000 individual shelf-keeping

20   units for literally billions of OTC packages.

21   The vast majority of OTC products have more

22   than one SKU. While each SKU has its own NDC number,

1   National Drug Code number, it may have a number of

2   different UPCs, between one and twelve, in order to

3   track different modes of distribution and sales for the

4   SKU of the product. And a UPC has a retail life of

5   about six months to many years.

6   Companies need to track SKUs individually by

7   their UPC in order to assess sales by account,

8   promotion success by package size, inventory

9   management, and package tracking in case of product

10 tampering or for a recall. This system is essential

11 for a robust business environment. It is very

12 efficient and it is very effective.

13   My third general set of points focus on the

14 scope and extent of a possible rule in this area. On

15 scope, given that the major use of OTCs is by the

16 consumer versus in institutions, should a barcode rule

17 apply where it would not be used, the self-care

18 consumer retail setting, but where it would be

19 potentially very disruptive to distribution? We think

20 not.

21   On extent, do you mandate the NDC as the

22 barcode on all OTCs, as the UPC or as a separate

1   barcode in addition to the UPC? Well, if the NDC were

2   mandated as the UPC, this would mean that we would not

3   be able to track all our channels of distribution and

4   sales models, and this would have a major small

5   business and larger business impact, unless -- unless

6   we were to frequently change the NDC, which would

7   increase manyfold the NDC listing and delisting

8   activities by FDA, industry, and institutions. And

9   there would be another source of medication errors.

10   Could you use two unidimensional barcodes, the

11   NDC and the UPC? Well, this wasn't recommended by the

12   panel this morning to have more than one barcode. It's

13   not recommended by the council that administers the

14   barcode. And we have heard of instances of confusion

15   in the retail area in terms of inventory and pricing

16   and other matters.

17   Could you go to different or combined

18   symbologies, reduced size symbology or composite

19   symbology? These are very attractive to us because

20   they record the size of that barcode, potentially

21   giving us more label space for consumer information.

22   But it's fair to say that this is a fast-

evolving area.   Suppliers are supportive of this, and

will be coming out with new adaptable scanners in the

near term.   Other industries, the fruit industry for

individual UPC labeling, want to go to reduced size

symbologies, as does the CD industry.

But this is in the future, I think the near

term future, because at the same time, we have a retail

environment that is highly invested in flatbed scanners

that don't read RSS easily or at all.   And this could

lead to pushback from retailers due to consumer

dissatisfaction and refusal to stock products.

Longer term, and maybe not so far in the

longer term, RSS, CS, and maybe other technologies

offer a longer term solution, and no regulation should

interfere with this kind of technological advance.

Again a comment on extent.   Do you barcode to

the individual OTC dose?   We don't think this would be

useful to the consumer in the self-care setting, as I

outlined earlier.   And this raises the general scope of

the rule.   And it would likely require that if this

were done, that we would have to delete the needed

opening instructions on the back of the blister pack.

1   Do you require a lot number and expiration

2   date? Well, they are already on the OTC label. And as

3   a practical matter, if you look at a unidimensional

4   barcode, as is currently used, you cannot put the lot

5   number and expiration date into that. You would

6   require some sort of composite symbology, which is not

7   available today in terms of a widespread production

8   form.

9   We simply don't have the validated systems or

10 processes for online application of lot number and

11 expiration date through barcoding technology. This

12 would likely require major retooling, and again, the

13 question of scope vis-a-vis OTCs comes in mind.

14   So as you consider scope and extent, and

15 phased-in implementation, does the immediate answer for

16 the fewer number of OTCs used in the hospital setting

17 reside with the repackager? And/or do you consider a

18 national information database linked to the UPC to be

19 the least disruptive to the overall distribution

20 channels, thereby allowing technology to advance and be

21 implemented at the retail level for even better

22 solutions in the future?

As a way of marshaling industry expertise and thinking on how to overcome the significant barriers surrounding this issue, we have formed an industry coalition on barcoding that includes PhRMA, GPHA, CHPA, and HDMA in order to address the stakeholder input from this meeting and provide future suggestions on how we might move forward in a feasible, practical, and cost-efficient way. Thank you.

MS. DOTZEL: Thank you, Dr. Soller.

Next we have Kay Gregory, who is here on behalf of the American Association of Blood Banks, America's Blood Centers, and the American Red Cross.

MS. GREGORY: Good afternoon. I'm pleased to be here today representing the blood banking community. Just by way of explanation, when we originally submitted our statement for the panel, we did not yet have approval from the American Red Cross. We're pleased to say that they have now joined in our statement. So I can truly say I'm here representing the entire blood banking community.

The American Association of Blood Banks is the professional society for over 8,000 individuals and

1 2,000 institutional members involved in blood banking

2 and transfusion medicine throughout the world. Our

3 members are responsible for virtually all of the blood

4 collected and more than 80 percent of the blood that is

5 transfused in the United States.

6   America's Blood Centers is an international

7 network of community-based blood centers that collects

8 nearly half of the U.S. blood supply and about 25

9 percent of the Canadian blood supply.

10   The American Red Cross, through its 36 blood

11 services regions, supplies approximately half of the

12 nation's blood for transfusion needs.

13   We welcome the opportunity to work with the

14 Food and Drug Administration and other interested

15 parties in developing regulations on barcode labeling

16 for human drug products, including biologics. Remember

17 that blood is classified both as a drug and as a

18 biologic.

19   The primary problem in transfusion medicine

20 indicates a need to reduce the human error, not the

21 problem you may all think would be most prevalent,

22 which is transmission of infectious diseases through

1   blood transfusion. That's really relatively minor and

2   has been pretty well conquered. Now we're looking for

3   other areas for improvement.

4   The introduction of new technologies such as

5   barcoding aimed at reducing the risk of human error can

6   save patient lives. We suggest that FDA adopt a broad

7   systems approach to the issue of minimizing the need

8   for human interface. Mandating the use of barcodes

9   without also considering how the barcode can be read

10   and how it will be utilized in various hospital systems

11   will not automatically reduce human error.

12   And while barcodes may offer one approach to

13   reducing transfusion errors, the FDA must not codify

14   policy that would limit the use of other equally

15   effective technologies in development, such as radio

16   frequency tagging.

17   The important issue is not to mandate the

18   particular symbology to be used. Rather, FDA and

19   providers should focus on requiring electronic data

20   interchange, and the definition and use of standard

21   data structures.

22   In answer to the questions that were posed in

1   the Federal Register notice, you should be aware that

2   blood and blood components are already barcoded.

3   Codabar has been in use since the 1980s. However, a

4   newer barcode, ISBT-128, has been successfully

5   introduced in other countries, and is currently under

6   consideration in the United States.

7   The FDA endorsed -- note the word "endorsed,"

8   not "mandated" -- ISBT-128 in a guidance document

9   published in June of 2000, "Guidance for Industry:

10   Recognition and Use of a Standard for the Uniform

11   Labeling of Blood and Blood Components."

12   It is also expected that future editions of

13   the AABB standards for blood banks and transfusion

14   services will require ISBT Code 128 if a facility is to

15   remain accredited by the AABB.

16   Since many of the considerations in the design

17   of ISBT-128 are also under consideration at this public

18   meeting, our written statement provides a detailed

19   description of considerations that led to adoption of

20   ISBT-128. I want to quickly highlight just a few of

21   them.

22   First, internationally agreed-upon placement

1   of labeling information. And note the word

2   "international." Internationally unique numbering

3   system. Internationally standardized product codes.

4   Encoding of date and time of collection, production,

5   and expiration.

6   Encoding of special testing results. Encoding

7   of manufacturer, catalog number, and lot numbers of

8   blood. And finally, most importantly, a mechanism for

9   continued maintenance and growth of the standard.

10   This slide shows an example of a labeled unit

11 of blood with all the various pieces of information

12 encoded in the barcode. Starting at the upper left is

13 the identification number, or what for many of you

14 would be considered the lot number. The ABO and Rh

15 type, which is extremely important.

16   The product number or the product code, as we

17 call it. The expiration date and time. Any special

18 testing results. And finally, although it's not

19 identified here, the barcode at the bottom left is the

20 product name. In this instance, it's red blood cells

21 with adenine saline added.

22   Now let me move to the other side of the

1   people that we represent, and that is the transfusion

2   medicine side, and talk about additional technologies

3   needed to prevent mistransfusion of the wrong unit of

4   blood.

5   Transfusion of incompatible blood, or

6   mistransfusion of blood, is the most common cause of

7   morbidity and mortality related to transfusion.

8   Serious errors are made at the time of sample

9   collection within the laboratory, at the moment of

10   blood issue from the laboratory, and at the bedside

11   when transfusion occurs.

12   ADO-incompatible transfusions due to

13   misidentification of recipients at the time of

14   transformation are the reported cause for as many as

15   two dozen patient deaths a year in the United States,

16   and such instances we know are under-reported.

17   The blood banking community encourages

18   research, development, and widespread application of

19   new technologies aimed at ensuring that the right

20   patient gets the right unit of blood. Some such

21   technologies, including methods of computerized

22   barcoding and patient wristbands, are already being

1   introduced in some individual hospitals.

2   Unfortunately, there has been only limited application

3   of existing technology to reduce mistransfusion.

4   Here are our recommendations, in conclusion.

5   The entire transfusion medicine community, both the

6   government and private agencies, must move forward to

7   encourage the use of promising technologies designed to

8   avoid patient harm. In this light, these are our

9   recommendations.

10   First of all, FDA should require the blood

11   bank community to adopt ISBT-128 or a comparable system

12   for labeling of blood or blood components. One of the

13   reasons for saying comparable is that we wanted to hear

14   what the outcome of this particular meeting would be,

15   although our preference right now would certainly be

16   for ISBT-128.

17   However, FDA should also recognize that this

18   cannot be done overnight. If it were mandated today,

19   it would require three to four years for

20   implementation. It will require significant resources

21   on the part of both industry and the agency. Because

22   blood bank systems are classified as medical devices,

1   they undergo 510(k) review. The agency must be

2   prepared to do such reviews in a timely manner.

3   Finally, we encourage the development and use

4   of patient and product identification systems for blood

5   products that will be compatible with whatever is

6   developed for drugs, pharmacy use, et cetera. Thank

7   you.

8   MS. DOTZEL: Thank you, Kay.

9   Next I'd like to invite Mary Grealey, who is

10   here on behalf of the Healthcare Leadership Coalition.

11   MS. GREALEY: Good afternoon, and thank you

12   for the opportunity to be here today and to share the

13   Healthcare Leadership Council's views on this vitally

14   important subject. Before I discuss our specific

15   recommendations, let me say a word about the Healthcare

16   Leadership Council and our approach to this issue of

17   barcoding.

18   The HLC is unique in that it represents all

19   sectors of the healthcare industry that would be

20   affected by the FDA's barcoding regulation. We are a

21   coalition of chief executives of hospitals and health

22   systems, pharmacies, pharmaceutical companies,

1   pharmaceutical and medical/surgical companies and

2   distributors, and medical device manufacturers. We

3   also represent pharmaceutical benefit managers as well

4   as health plans. As you can see, a pretty diverse

5   group, but all would be affected by this regulation.

6   Two years ago, the HLC members created a CEO-

7   level task force on patient safety, a task force that

8   has focused on measurable, evidence-based, and

9   achievable solutions to the patient safety challenges

10 our nations face.

11   This task force has determined that electronic

12 verification of drugs at the point of administration

13 should be a high priority initiative. We believe

14 strongly that automated drug identification has the

15 potential to greatly limit medication errors.

16   The remainder of my statement will be divided

17 into two sections. First, I will offer our broad

18 guidelines on automated identification of medical

19 products that have been developed by our HLC members,

20 and then I'll share with you some of our specific

21 recommendations.

22   I cannot stress strongly enough a critical

element in the recommendations I'm about to offer for

your consideration. They reflect a consensus of our

membership. In other words, we have reached common

understanding between the healthcare providers, product

distributors, and manufacturers, who will each play a

critical role in the success of using barcoding to

auto-identify medical products.

And it goes without saying that the success of

an FDA regulatory standard hinges strongly upon the

cooperation of numerous parties along the drug supply

chain, from the creators of the barcode printing

equipment to the nurse that administers that dose at

the bedside. We believe the following suggestions and

suggested guidelines will lead to a harmonious and

effective system.

First, we must be pragmatic. Auto-

identification standards should support the highest

attainable level of safety through the most feasible

and cost-efficient approach that can be implemented in

the shortest period of time.

Second, the regulatory standards should build

upon and not disrupt current market forces. Many

149

pharmaceutical companies have already initiated the

printing of barcodes wherever possible on their unit of

use packages. An increasing number of hospitals are

adding auto-identification systems to their hospitals.

We should not discourage this progress, and we

certainly should not discourage unit of dose packaging

by pursuing requirements that are overly expensive and

highly difficult to implement.

Third, an FDA barcode labeling regulation

should, over the long term, result in reducing or at

least not increasing the workforce needs of the

healthcare system. Many healthcare providers, as many

of us know, are already trying to deal with workforce

shortages, and their personnel are stretched very

thinly at this point. A new regulation should not

exacerbate this problem.

And finally, the FDA should construct a

regulation flexible enough to accommodate new and more

effective technologies as they become available.

Barcoding may be the auto-identification choice of

technology today, but radio frequency, data matrix, or

other technologies may prove to be more effective and

1   less costly in the future. We must not preclude

2   technological advances.

3   These four guidelines, we believe, should

4   comprise the foundation of any FDA barcoding regulation

5   that can expect wide acceptance and successful

6   implementation throughout the healthcare system.

7   Now, having laid that foundation, let me move

8   on to eight specific recommendations the HLC offers in

9   response to the FDA's notice.

10   Number one, if the FDA requires barcoding,

11   then this requirement should be limited to unit of dose

12   drug and biologic packaging used only in the

13   institutional environment. This should include both

14   prescription and over-the-counter medications.

15   Number two, initially barcode data element

16   requirements should be limited to the National Drug

17   Code number, the NDC that we've heard so much about

18   today. The NDC contains all of the necessary

19   information to ensure that the patient is given the

20   right drug in the right dosage.

21   Lot number and expiration date should only be

22   considered when the technology for printing dense

1 barcodes is more widely available, and when we have

2 research showing that patient safety is enhanced to a

3 degree that warrants the difficulty and cost of

4 implementing this additional information. The FDA

5 already requires lot number and expiration date to be

6 in human-readable form on the drug package, and at this

7 time this should be sufficient.

8   Number three, in the near term the FDA should

9 not require the application of barcodes beyond the

10 currently widely used linear, one-dimensional barcode

11 symbology. Requiring the immediate use of reduced-

12 space symbology or two-dimensional barcodes would

13 substantially increase manufacturing and packaging cost

14 and could also reduce printing and verification

15 productivity by up to 40 percent, according to our

16 technical experts. Also, existing hospital barcode

17 scanning equipment would have to be reprogrammed to

18 read newly configured codes.

19   Let me be clear: We do not advocate

20 prohibiting the use of more advanced technologies or

21 symbologies. However, we do believe that the FDA

22 should conduct research and convene the appropriate

1   stakeholders to determine an appropriate timeline for

2   introducing specific standards for the newer developing

3   auto-identification technologies.

4   Number four, we ask that the FDA not limit

5   flexibility by mandating the specific location of the

6   barcode on a package. This kind of specificity is not

7   needed to protect patient safety and could perhaps

8   unduly increase costs.

9   Number five, barcode requirements should apply

10   to containers that are the most critical to medication

11   safety. This includes unit of dose containers. An

12   additional consideration for the FDA is that unit of

13   use containers come in various shapes and sizes, from

14   oral solids and topical creams to prepackaged syringes

15   and vials and ampules.

16   Unit of use containers that are small or

17   irregularly shaped are more difficult to print with

18   barcodes, especially using automated printing systems.

19   Consideration should be given to this particular but

20   very important difficulty.

21   Number six, we believe that the FDA should

22   reevaluate the annual label review process with respect

1 to label changes that may be necessary to accommodate

2 barcodes. Creating a fast track process and

3 eliminating certain element size and data requirements

4 would help accommodate the placement of the barcodes.

5 Number seven, careful thought must be given to

6 the phase-in schedule of any regulation. Consideration

7 must be given to the time and expense involved, and

8 retooling packaging operations, purchasing new printing

9 and verification equipment, redesigning packaging

10 artwork, and refiling for label approvals. The last

11 thing we want to do is to discourage unit of use drug

12 packaging with an unfeasible phase-in schedule.

13 Let's also keep in mind that less than

14 5 percent of the hospitals in this country have the

15 hardware, software, and training programs in place to

16 conduct bedside barcoding at this time. In determining

17 the effective date of this regulation, we need to

18 assure hospitals that sustainable barcoding equipment

19 and software compatible with their existing information

20 technology will be available.

21 And finally, number eight, the FDA or other

22 agencies within Health and Human Services should

1   consider including a grant program to assist hospitals

2   in acquiring the technology necessary to implement

3   bedside auto-identification of medications.

4   Let me close by saying that I can't emphasize

5   strongly enough the commitment on the part of all

6   sectors of the healthcare industry to take the steps

7   necessary to enhance safety and to reduce the

8   possibility of medical errors.

9   Significant progress is taking place. Earlier

10 this week, for example, one of our HLC members, Abbott

11 Laboratories, announced that it will have barcodes on

12 all of its hospital-dispensed drugs by early next year.

13 This is but one example of the advancement in the

14 marketplace that is occurring across the spectrum of

15 American healthcare, and it is essential that any

16 regulation facilitate and not inhibit this progress.

17   The FDA needs to take great care that

18 regulations aren't so costly or so difficult to

19 implement that they result in unintended consequences,

20 such as hindering the production of unit dose

21 packaging. And if we are to realize the broad

22 nationwide gains in patient safety through barcoding,

1 then we need to ensure that hospitals have access to

2 the technologies essential to make it happen at the

3 patient's bedside.

4   On behalf of the members of the Healthcare

5 Leadership Council, I'd like to thank you for the

6 opportunity to address this issue, and we stand ready

7 to assist you in any way possible for the safety of all

8 patients. Thank you.

9   MS. DOTZEL: Thank you, Mary.

10   The last speaker on our panel this afternoon

11 is Tess Cammack, who's here on behalf of AdvaMed.

12   MS. CAMMACK: Good afternoon. Thank you for

13 this opportunity to present AdvaMed's views on this

14 important issue. I am Tess Cammack, associate vice

15 president of technology and regulatory affairs for the

16 Advanced Medical Technology Association, or AdvaMed.

17   AdvaMed is the largest medical technology

18 association in the world, representing more than 1100

19 manufacturers of medical devices, diagnostic products,

20 and health information systems, a diverse range of

21 hundreds of thousands of distinct products.

22   AdvaMed and its members are committed to the

1 voluntary use of industry-approved automatic

2 identification for medical devices where it is

3 economically and technically feasible, and where it is

4 clinically practical.

5 My use of the term "automatic identification"

6 is carefully chosen. We all recognize traditional

7 barcodes used on retail packages, but there are other

8 configurations, including radio frequency technology,

9 that uses an embedded chip.

10 All these technologies can use various data

11 structures under the universal product numbering

12 system, and most modern scanning technology can read

13 them all. Because these technologies will continue to

14 evolve, we refer to automatic identification rather

15 than barcoding, which could inappropriately lock

16 industry into one standard, one coding language, or one

17 technology.

18 AdvaMed is concerned that the request for FDA

19 to require barcoding on all medical devices falls short

20 of the needs of a heterogeneous industry. Devices come

21 in all sizes. They are packaged individually or by the

22 hundreds. They are made from a wide range of materials

1   requiring various sterilization and storage needs.

2   They may be designed for single use or multiple use.

3   Their clinical applications vary greatly.

4   I am here today to challenge us all to see the

5   unique design characteristics and usages of devices as

6   significantly different from drugs and biologics,

7   particularly in light of the agency's interest in

8   exploring whether UPNs on devices can improve patient

9   safety.

10   For this reason, AdvaMed recommends that FDA

11   not include devices in its forthcoming rule on

12   barcoding for drugs and biologics, and that any

13   consideration of auto-identification for devices be

14   addressed separately.

15   Industry surveys indicate that from 1995 to

16   1997, there was approximately 30 percent more UPNs on

17   devices at the unit of use level, and nearly 17 percent

18   more on the shelf-pack level. Unfortunately, this

19   older data are soft and there is a need for updated,

20   unbiased surveys that look at not only the number of

21   UPNs on devices, but also the extent to which

22   healthcare professionals utilize the products that are

1   coded and why they do so. Even so, the data we do have

2   confirm that manufacturers, without regulation,

3   increasingly are auto-identifying medical devices.

4   Decisions are best made when manufacturers

5   work with healthcare professionals to clearly identify

6   the goals and practical limitations of auto-

7   identification. They may ask how a device is used, how

8   often it's used, how it's packaged. The manufacturer

9   will consider lot size, device and packaging size, and

10   surface material.

11   They should consider how hospital protocols

12   might be changed by the use of UPNs, which format might

13   be appropriate, and at what level of packaging UPNs

14   should be used. All this is a process to determine

15   whether the expected benefits warrant the additional

16   burden to the healthcare system.

17   Manufacturers use UPNs on devices for various

18   reasons. Most temporary and permanent orthopedic

19   implants, for example, are auto-ID'd to provide

20   traceability. Other products are auto-ID'd to assist

21   in inventory control. And while some devices may be

22   auto-ID'd to reduce medical errors, there is a notable

1 lack of statistically significant data to indicate that

2 UPNs on all medical devices would reduce medical

3 errors.

4 There are, unfortunately, significant

5 obstacles to auto-identifying medical devices. The

6 packaging material may inhibit the use of printable

7 codes. Small devices with limited packaging may need

8 to rely on two-dimensional symbols or RF technology

9 instead of a linear barcode, or they may require

10 larger, costlier packages.

11 Because a UPN may be applied at different

12 levels of packaging, the UPN may not be present at the

13 point of use, especially for multiple use devices that

14 have been sterilized in-house.

15 Most device companies are small firms for

16 whom, in particular, auto-ID reflects significant

17 investments. The costs to hire technology experts and

18 purchase printers, scanners, and software must be

19 weighed against the expected benefits of auto-ID.

20 Identifying each and every throat swab at the unit of

21 use level, for example, would not be practical or

22 beneficial.

1   On the other end of the spectrum is capital

2   equipment, for which auto-identification at the unit of

3   use may not be appropriate. What would the patient

4   safety benefit be in requiring UPNs on these products?

5

6   These examples tell us several things about

7   industry working with its customers to voluntarily

8   apply UPNs to certain devices. There is no one-size-

9   fits-all approach because medical devices come in too

10 many shapes and sizes.

11   They are packaged differently and in different

12 quantities. They may be used singly or multiple times.

13 They are manufactured in lot sizes that vary from firm

14 to firm. Requiring auto-identification on all devices

15 could unnecessarily increase healthcare costs without

16 improving patient safety.

17   This brings us to the heart of my discussion,

18 whether FDA should require auto-identification on

19 devices to reduce medical errors. A 1999 Institutes of

20 Medicine Report suggests that medication errors,

21 transcription errors, user errors, staffing shortages,

22 and lack of training are the prevailing root causes of

1   medical errors.

2   Those attributed to medical technology are

3   notably absent from this list. You could argue,

4   therefore, that a mandate to auto-ID all devices would

5   have only proportional success and would impose a

6   significant cost burden on the healthcare system.

7   Secondly, it's unclear how healthcare

8   professionals are expected to use auto-IDs on devices

9   to improve patient safety. For drugs, the application

10   is certainly clearer. A patient's list of drugs,

11   dosages, administration times, can be benchmarked

12   against actual usage to minimize the risk of errors.

13   But a similar expectation to benchmark device

14   usage is far more vague. A UPN is but one piece of a

15   system that requires a commitment to scan products,

16   identify patients, update code information, and analyze

17   data if benefits are to be realized. Increased patient

18   safety may be attainable for only a subset of medical

19   devices, depending on the nature of the device and its

20   use in a clinical setting.

21   A UPN identifies a product. It provides

22   traceability, not patient safety. For instances where

1   FDA has determined that traceability is necessary,

2   device tracking has already been ordered. Effective

3   systems to track devices have been in place for years,

4   and applying a UPN to a device will not necessarily

5   improve this process.

6   Clearly, auto-identification is not a silver

7   bullet to resolve medical device-related errors. Firms

8   have already auto-ID'd thousands of devices, and they

9   will continue to work with customers to decide which

10   other products should be auto-ID'd. It is a dynamic

11   process that moves forward, albeit deliberately, in a

12   way that is responsive to customer needs and is cost-

13   effective, employing UPNs selectively where benefits

14   can be realized.

15   To summarize, AdvaMed encourages greater

16   communications between healthcare stakeholders to

17   ensure that automatic identification is voluntarily

18   applied to devices where it is economically and

19   technically feasible and where it is clinically

20   practical.

21   AdvaMed strongly encourages providers and

22   purchasers to fully utilize UPNs when they appear on

1   medical devices. Using auto-ID to prevent medical

2   errors requires not only that manufacturers apply a

3   UPN, but also that users commit to its appropriate

4   employment.

5   AdvaMed supports the voluntary use of UPNs on

6   medical devices, which allows for the use of industry-

7   approved UCC/EAN or HBIC standards, a decision that

8   reflects the clinical use of devices, the interests of

9   healthcare professionals, and the challenges faced by

10   manufacturers in auto-identifying medical technology.

11   For all these reasons, AdvaMed strongly

12   encourages FDA to recognize that the unique diversity

13   of medical devices is so significant that they should

14   be excluded from the agency's forthcoming rule on

15   barcoding for drugs and biologics, and addressed

16   separately.

17   We look forward to working with the agency and

18   stakeholders on this, and we appreciate your attention

19   and interest today. Thank you.

20   MS. DOTZEL: Thank you, Tess. Now I'd like to

21   give the FDA panel members an opportunity to ask

22   questions of our second panel.

1 DR. GALSON: I've got a question for

2 Dr. Soller.

3 If we require barcodes on prescription drugs

4 but not over-the-counter drugs, how do you anticipate

5 dealing with the issue of all the over-the-counter

6 drugs used in hospital settings, particularly ones that

7 are used a lot, like analgesics, where the doses may be

8 very important and we really want to make sure to avoid

9 errors?

10 DR. SOLLER: Let me comment on that. That's a

11 good question, and I tried to address our view in my

12 comments. I think in looking at a proposed rule, it's

13 important to consider scope, and as I mentioned, to

14 think about whether requiring a barcode or a new type

15 of barcode or a revision of the current barcode across

16 an entire category where the intent of the rule would

17 not have necessarily a direct benefit, but where that

18 rule might have a benefit in a subset. That scope

19 should be looked at very carefully.

20 And then also, as I put through some of the

21 comments that our group has been concerned with in

22 terms of what might be a change to the UPC, to think

1　about ways where, you know, on the other hand -- just

2　stepping back for a moment, on the other hand you might

3　think about a perfect solution that's totally systems

4　perform and then plunked into operation.

5　　　　　And that clearly can't happen, particularly

6　when the machinery is simply not there. And so you can

7　imagine the industry view, being required to do

8　something when you wonder whether it's even going to be

9　used by the end user. And that is balanced by a

10　perspective that it's important to try and find a way

11　to address medication errors, and there's a commitment

12　by the industry to do that.

13　　　　　So how do you balance it? And do you go to

14　the perfect solution, or do you look for some sort of

15　phased-in approach? And what I was trying to suggest

16　from our group, a willingness to dialogue on this, but

17　to think about the repackager as a vehicle here where

18　very specific coding symbology could be worked out with

19　institutions interested in moving forward, and I

20　suspect that will be an incremental march among the

21　institutions and not somebody that will occur quickly.

22　　　　　And also to think, in that regard, there's --

1   currently ongoing for NDA products, looking at

2   establishing an informational database on labeling.

3   Can that be taken to a next step that might allow

4   linkage of current UPC which is being used and

5   electronic updating, and then access by various

6   institutions that will slowly move forward to do this.

7   So I think the public health solution is not

8   always a perfect one, but is one that may recognize all

9   the different facets and look for the kind of approach,

10   near, mid, and longer term, that would be appropriate.

11   And our group certainly endorses the kind of regulation

12   that would not put a damper on technological advances,

13   whether it's radio frequency or RSS or CS. All of

14   these are very attractive options for the industry to

15   want to explore.

16   DR. GALSON: Just a quick follow-up. Just as

17   a point of information, really, are your products in

18   general packaged separately for institutional users, or

19   is it -- do they get the same --

20   DR. SOLLER: No. We actually have very little

21   control of that. The institutions will go to

22   distributors. We would sell to distributors. And then

1 that stream of distribution is essentially out of our

2 control.

3   And the institution would then go to the

4 distributor or the repackager. You know, the VA goes

5 to a repackager -- or may do it itself; I don't know

6 that system -- and then work out whatever supply they

7 would need.

8   So we don't -- we've looked into that. We do

9 not have a segmented hospital-directed market that

10 represents any kind of significant size of our

11 industry.

12   MS. GREALEY: I'd just like to comment on

13 that. I think Dr. Soller has raised some very

14 important points there, and really has defined well

15 rather than -- and this may be too harsh of a word --

16 overreaching by trying to capture every over-the-

17 counter medication, where what we're really trying to

18 get at is what's used at the patient bedside, that yes,

19 going through distributors, repackagers, may be a way

20 to approach that that would get at what you're trying

21 to get.

22   DR. GALSON: Thanks.

1   Dr. FEIGAL: I had a comment on a device area.

2   I mean, I appreciate the suggestion to change the

3   terminology to auto-identification and not lock us into

4   a specific technology because there are some pretty

5   exciting technology changes in auto-identification,

6   some of which are very small and may be cheaper than

7   even printing, just as now magnetic storage is cheaper

8   than paper, and who would have thought we would be at

9   that point.

10   There are some unique challenges in the device

11   area for hospitals and healthcare facilities. And one

12   of them is tracking products which have been recalled.

13   And this may be a safety issue that is different for

14   devices than it is for drugs, where the issue, the

15   safety issue, may be more focused on getting the right

16   drug to the right patient.

17   Every year there's between 1,000 and 1400

18   medical device recalls, and actually that number has

19   been growing. And that's just the number of recalls.

20   The actual number of products recalled every year is in

21   the millions. In fact, I think one year we topped out

22   at four billion units of products recalled.

1   Just to highlight one example this year, there

2   was a company whose products were recalled who were

3   shipping 10,000 surgical instruments a month which were

4   not sterilized. And one of the difficulties in

5   hospitals finding these is all of the paths of

6   consignees and middlemen and so forth.

7   But it would seem that there would be an

8   interest on the hospital side of being able to rapidly

9   respond and identify inventories and to be able to work

10   with these types of products. Typically, in the

11   recalls, it's not unusual to not even get 5 percent of

12   the products back or have the hospitals even to be able

13   to identify 5 percent of the products which are

14   defective and have been recalled.

15   And it's a little hard to explain why the

16   performance is so difficult in this area. But it seems

17   like this is one of the potential areas. It's more on

18   the inventory control side of things, but a few years

19   back when a manufacturer was shipping iodine that was

20   grossly contaminated with pseudomonas -- in fact, the

21   blood industry picked that up as they cultured the

22   product looking for another product -- there wasn't any

1   way to trace where any of that product had gone. It

2   affected over 140 different device manufacturers. But

3   in terms of patient safety, there was no way to really

4   tell or track where any of that had gone or to identify

5   was it a significant risk or, you know, wasn't it.

6   I realize these things create certain

7   liability concerns. But I'd be interested in your

8   comments on whether or not there are tools that are

9   needed that would help industry meet its

10 responsibilities a little better than it's currently

11 doing in the recall area, where its performance is

12 fairly inadequate.

13   MS. CAMMACK: You raise a very good issue.

14 And I think the diversity of the industry underscores

15 why this needs to be looked at more carefully and why

16 are recalls -- you said that it's difficult to know why

17 they may or may not be working efficiently.

18   Barcoding may or may not be the answer to

19 that. This is one of the reasons why we'd like to be

20 working more closely with the stakeholders to determine

21 if things aren't going correctly as they should, or the

22 information isn't coming from manufacturers as rapidly

1   or as efficiently as it should. Why is that occurring?

2   Can barcoding resolve that? Maybe it can assist it.

3   Maybe other things are needed as well.

4   But to have a blanket approach for such a

5   wide, diverse industry and say, let's put barcoding on

6   everything so we can improve recalls, are you really

7   going to get your expected benefit at the expense of

8   putting that burden on industry?

9   I think many of the questions that we ask

10   about coding devices, we have to go through that

11   balance and see if we're achieving it. And it comes

12   back -- maybe where we need to start is being clear on

13   the starting data on this.

14   I think it's been suggested a couple of times

15   today we need to do a better job of understanding where

16   products are being coded, how those products are being

17   used in the clinical setting, and how has it been

18   effective in improving patient safety, before we know

19   where are the applications it would be appropriate.

20   MS. GIESER: We've heard some discussion this

21   morning, and again this afternoon, about potential

22   implementation periods, anywhere from possibly as soon

1   as one year, two to three years, and maybe four years,

2   I believe I heard.

3   I wonder if the panel would speak to --

4   elaborate more on how you would benefit from longer

5   implementation periods. Is it reduced costs? Are

6   there some products that are more problematic to you so

7   that you need more time? Can you elaborate?

8   DR. JOHNSON: If I can start, anyway, I think

9   a key issue -- the first issue that it would affect

10   cost and implementation is what data elements are going

11   to be required. Speaking for pharmaceuticals, if it's

12   NDC number only, then the implementation time is more

13   of a package design question.

14   And then how long does it take to get the

15   barcode or some auto-identification code placed on the

16   artwork; where necessary, to get that approved; to get

17   it to the printers; to get it phased in; and to get it

18   out into the marketplace.

19   And that is what we believe we can do two to

20   three years. Again, you've got to consider the wide

21   variety of packages. Some of them already have

22   barcodes. I work for a company that has been working

1   very diligently and made commitments to implement

2   barcodes on injectables, but I can tell you there have

3   been literally probably tens of thousands of manhours

4   of work just to put the NDC number on that subset of

5   our total group of pharmaceutical products.

6   So if you say we have to do other data

7   elements, frankly, we're not exactly sure how to even

8   do that. So to give an estimate on how long it would

9   take becomes very problematic.

10   So I think that deciding what data elements

11 are required, and then considering the wide variety of

12 packages, some will be able to be implemented much more

13 quickly than others.

14   MS. GIESER: If we just spoke to the NDC code

15 only, just for ballpark discussions?

16   DR. JOHNSON: Again, in talking with the other

17 member PhRMA companies, we felt like we could achieve

18 that for most of the products within two to three

19 years. And given that there are some products that are

20 very tiny, there would have to be some discussion on

21 whether or not we would have to remove so much text or

22 shrink the text down that that would be defeating the

1   purpose.

2   Because we have to remember, for a long time

3   to come, we have to maintain both human-readable and

4   machine-readable. And if we have unreadable human-

5   readable text, is that going to contribute to

6   medication error reduction or actually make that worse?

7   So there are some that we just don't know of a

8   solution, even with just the NDC number.

9   DR. SOLLER: Just a comment. Again, I would

10   agree. It depends upon scope and extent. And at least

11   as it would relate to OTCs, I don't think it's just a

12   package design question. I think there's a clear

13   distinction between the PhRMA-related products and the

14   CHPA OTC drug-related products in this regard.

15   I think there are issues relating to listing

16   and delisting. We would see a manyfold increase in

17   that activity. And the impact of that on the system

18   and how that is updated and the validation of that

19   system, I think, would be very important if we're truly

20   interested in going that route and thinking that

21   therefore the many different NDC numbers would now

22   represent how we would track our channels of trade.

1   I don't think personally that -- nor does my

2   group think that that's the best approach. And if

3   you're looking at mandating it down to unit dose or lot

4   number or expiration date, I can tell you that that

5   will require major packaging changes on the former and

6   major retooling, if it's going to be online lot number

7   and expiration printing through barcoding. And that is

8   a very long and length process.

9   With the question noted earlier, to what

10   extent does that really add to patient safety? And so

11   I would think there should be an evidence-based

12   approach there particularly.

13   Last comment, just to reiterate what I said to

14   Dr. Galson earlier: Looking at a repackaging and/or an

15   informational database solution on the OTC side is a

16   much nearer-term type of solution.

17   DR. BENDE: Yes. I mean, just to echo some of

18   the things that have been said, I think implementation

19   time comes after planning and agreement of standards

20   time. And I think we're just beginning the debate

21   about -- and the discussion about that, I hope, now and

22   such that we're hearing all these different

technologies aside from barcoding, such as, you know,

radio transmitters and what have you.

Hopefully, there will be a standardized data

format that they all read into, or there'll be some

goal that we can all agree upon that is best -- you

know, that our end user friends can tell us is going to

be the best for them to use, actually, and to actually

give a benefit.

So in terms of giving it a timetable, I think

the first order of business is to agree upon some

standards that all of the different technologies would

read into. So again, I think we're -- we need probably

some good time for planning.

You know, I've heard from one or more of our

member companies that we would hope that this wouldn't

turn into a situation as difficult as Part 11 has been.

So with that in mind, I think the planning and

agreement upon standards throughout the industry -- the

PhRMA companies, GPHA, CHPA, et cetera -- and I think

you heard from us that at least some of us have already

agreed to talk together, to work together, to move

toward that. So I think we're really at that stage

1   rather than the implementation stage.

2   MS. GREALEY: I just wanted to reinforce the

3   importance of the data elements that everyone has

4   touched on here. And we discussed it at length with

5   technical experts, again representing all the different

6   sectors of the healthcare industry, that if we can keep

7   it to the NDC, then we can move ahead and we can move

8   ahead a lot more quickly than if we do try to do

9   something that includes lot and expiration number

10   immediately; that right now, that that would so reduce

11   the productivity of the manufacturers because there

12   doesn't really exist equipment that would allow them to

13   verify and to package at a high rate at their current

14   rate of speed if you were to require that additional

15   information.

16   So it's going to be a constant balancing act.

17   How quickly do you want to move ahead? How costly do

18   you want it to be? How easy do we want it to be

19   implemented? And how much can we achieve in terms of

20   improving patient safety by limiting the data elements

21   that would be required?

22   And I don't think we should lose sight of what

1 is already occurring in the marketplace. The

2 marketplace is driving a lot of this as well. I think

3 you can help it along, but manufacturers and others are

4 stepping up because their customers are demanding that

5 they do it.

6   MS. GREGORY: I think from the blood banking

7 industry, we're a little ahead of everybody else.

8 We've clearly already identified all of the information

9 that we need to capture. We've even been capturing

10 some of it under Codabar. The problem is that that's

11 an outdated symbology and we need to move on to

12 something else.

13   I think for us, the real problem is cost, as

14 everybody has alluded to, but also competing

15 priorities, because what we will need to do is to

16 convert all of our software systems that we're

17 currently using so that we can utilize all these

18 elements most effectively.

19   And the issue is, okay, do we do that? Do we

20 do nucleic acid testing? Do we computerize donor

21 screening? Exactly which of the safety initiatives

22 that we're working on -- where does it fall in line?

1 And I think that's really our big issue.

2 And one of the things is because FDA hasn't

3 mandated it, it kind of falls way down here in

4 comparison to those things that FDA maybe has already

5 mandated.

6 MS. CAMMACK: I'd like to echo a number of the

7 comments that were made on the panel, but add to that

8 as well on the device side, for many of our

9 companies -- I think it's 75 percent of the industry

10 are representative of small companies. And they're not

11 going to have the resources that some of the larger

12 companies have. Maybe they haven't even, you know,

13 entered this arena yet.

14 So they're going to have significant startup

15 costs. So what one company is doing versus a larger

16 company, per se, they may be able to move on a faster

17 track. And it's hard to come up with one target date

18 for how implementation would happen.

19 Or even at a large company level, they may

20 have manufacturing production lines in different

21 countries. Technology used in one country may not be

22 the same as used in another to put the code on

1   something. And if they're having to update those or

2   change those, you know, they're going to be doubly

3   challenged to meet the requirements that would be set

4   forth.

5   So I think the voluntary process that we have

6   is moving forward, and it results in some of the best

7   decisions because it allows manufacturers to add coding

8   when it's responsive to customer needs. And often, it

9   can be done at a time when other labeling changes were

10 done as well, since you have to consider how this is

11 all going to fit on a label.

12   MS. MAHONEY: I have a question, Kay, for you.

13 The blood industry, as you said, has been using

14 barcoding for a while. And I wanted to know whether

15 you have a sense of how that had resulted in reduced

16 errors, and what you see if you think ISBT will result

17 in more reduction in errors, and why.

18   MS. GREGORY: I think that ISBT will result in

19 reduction of errors on what we call the manufacturing

20 side or the blood collection side. I'm not sure how it

21 will result in reduction of errors on the transfusion

22 side unless it is tied in to patient identification

1   systems.

2   We clearly want to go that direction, so that

3   you identify the patient. You identify the caregiver.

4   You identify the unit. And you notice, there are a

5   number of elements of information that need to be

6   tracked for a unit of blood that are somewhat different

7   from what you're talking about on your drugs. For

8   instance, I don't think the NDC code would do anything

9   for us because we can't get all of that information in

10   there.

11   I think one of the big issues may have to do

12   with something else that Dr. Feigal has talked about,

13   and that is tracking. Because one of the advantages of

14   ISBT-128 is that there is a unique identifier.

15   The way things work right now, I might have a

16   blood center, and I use identification code 12345 as

17   identification of a particular donor. Someone else may

18   have a collection center, and they're also using 12345.

19

20   So if I'm a hospital, I get 12345, and now I

21   have to make sure that I can track, well, exactly which

22   place sent me this. Well, this is all built into the

1 ISBT code, so that it can all be barcoded. And I think

2 the tracking will be much simpler for that reason.

3 MS. MAHONEY: And then just a question for

4 PhRMA and the generics industry. I think I heard

5 support for the concept of some sort of coding. And I

6 don't think I heard either of you distinguish between

7 the prescription drugs versus the OTC.

8 Do you have a difference of opinion with

9 regard to those products?

10 DR. JOHNSON: I think PhRMA's focus has been

11 on prescription medications and vaccines. There are

12 some questions about clinical supplies that may present

13 some special concerns. And we hadn't come to a

14 conclusion about samples, although we heard some

15 comments earlier today. So we did not focus on OTC

16 products.

17 MR. BENDE: Yes. We didn't really focus on

18 that, either. I mean, we're talking more specifically

19 about prescription drugs. And I would just like to

20 point out that Bill and I have spoken about this issue,

21 and some of our members are member companies that we

22 actually share member companies, a couple of them, you

1   know.

2   So it's an issue that -- but primarily, GPHA

3   is really more -- we're more focused on the

4   prescription drugs. But, you know, we haven't really

5   weighed in specifically on the OTC problem. But

6   clearly it's of interest to some of our members.

7   DR. SOLLER: We were unanimous in our view.

8   MR. BECKERMAN: I've got a question for

9   AdvaMed. Recognizing the diversity of medical device

10   manufacturers and knowing that you represent a very

11   broad range of them, does AdvaMed have a position on

12   combination devices, things that incorporate both drugs

13   and devices?

14   MS. CAMMACK: Well, I think we'd have to

15   follow how those are regulated by the Agency.

16   MR. BECKERMAN: And I guess, sort of to follow

17   up, a related question. There was some discussion this

18   morning about stratifying medical devices dealing with

19   different classes of devices in different ways. I

20   wanted to see if you would address that, whether you

21   view that as a workable solution.

22   MS. CAMMACK: I think that's an excellent

1   place to start when we talk more with stakeholders.

2   And probably the best way to begin stratifying that is

3   to go back to where are most medical errors occurring

4   and what role do medical devices play in those errors

5   then and is there a way then that barcoding could -- or

6   auto-identification could reduce those opportunities.

7   MS. DOTZEL: I just have one last question.

8   This morning we heard a lot, I think, from the health

9   professional panel -- a lot of, hurry up, FDA. We're

10 waiting for you to do this. You should have done this.

11 You know, get moving. Let's get this out there. And

12 this afternoon, I think we're hearing a little bit more

13 of, whoa, slow down. Create a task force. Study this

14 a little bit more.

15   Obviously, in a perfect world, we would be

16 able to, you know, bring in every piece of information

17 that's out there before we made any regulatory

18 decision. Obviously, if we waited for all that, we'd

19 never make a regulatory decision.

20   And so just your comments on how we kind of

21 balance the need for getting as much information as we

22 possibly can before making a decision on where to go on

1 this rule, with the need to actually do something to

2 address the problems that we're trying to address.

3   MS. GREALEY: I was struck by reading the

4 statements and listening this morning: I think there

5 is much more consensus here than perhaps was apparent

6 to you. They weren't saying, try to do everything all

7 at once.

8   I think they recognized a lot of what you

9 heard here this afternoon: NDC. Linear symbology.

10 It's something that is much more widespread. We could

11 do it now. Let's try and accomplish that.

12   And then, yes, you do need to bring in the

13 stakeholders for some of these other issues that I

14 think everyone on both panels sort of admitted: You

15 know, we're not quite sure how we could do it on

16 smaller vials, ampules, those sorts of things. How do

17 we work in lot and expiration number?

18   I think everyone has had more time since the

19 initial notice had been produced to really look into

20 this, bring their technical experts in. But I think

21 there is a lot of consensus around there are some

22 things that we could do in the near time. And then,

1 yes, let's be firm about establishing a timeline for

2 accomplishing the others, not let it go by the wayside.

3   DR. BENDE: I think I would tend to agree with

4 that. But I think it doesn't benefit anyone to move

5 forward too quickly when we hear our friends from the

6 hospital association say, for example, that -- you

7 know, I don't think they want to have to juggle six

8 different kinds of scanners because there are six

9 different kinds of technologies that people could use

10 to code product.

11   So we really have to start there and say, can

12 we standardize in some way? Can we make this as

13 streamlined as possible to benefit the manufacturers as

14 well, so that there's one -- you know, there's one

15 standard data readout, and give the hospitals and the

16 end users ballpark what they have to -- you know,

17 ballpark a little bit better so they can predict what

18 their users are going to need and they'll have to

19 purchase for them.

20   So I would even say that just the NDC number

21 probably isn't just something we could do, you know, in

22 a couple of months or something like that because there

1   is no standard. I mean, what kind of data -- we heard

2   ideas from Dr. Combes, I believe, about how this could

3   read into a -- this is part of a data issue.

4   So what database, what formats is this going

5   to be going into? Can the hospitals and all the

6   providers agree on a format that it reads into, so that

7   we can get this settled at the beginning, and then we

8   don't have manufacturers having to make changes, you

9   know, in six months for NDC numbers and then in two

10   years for everything else, and they wind up having to

11   implement multiple systems.

12   So I think to do this right for patients,

13   even, it needs to be thought out beforehand, before we

14   even say, well, let's do NDC numbers and worry about

15   everything else. I think we need to start from the

16   beginning and really map this out.

17   MS. CAMMACK: I think for the device industry,

18   we see ourselves as being a very distinct position from

19   drugs and biologics, so much so that I think, when you

20   look at how coding can help improve patient safety, it

21   seems to be a lot more obvious on the drugs and

22   biologics side than it is on the device side.

1   And we feel that there could be some

2   inadvertent or unintended consequences if medical

3   devices were at this time hurried up or rushed into a

4   bill that is really more appropriately addressing drugs

5   and biologics.

6   I think the kind of discussion that's happened

7   today, we could have a full day -- a week-long meeting

8   alone just on devices. I think there are some unique

9   issues there that have to be teased out on a product-

10 by-product category basis.

11   And to suggest that this is -- the time is

12 right to include devices in this forthcoming rule with

13 drugs and biologics, we just think that that's a

14 premature decision. And we may not reap the intended

15 benefits if we progress at that pace.

16   DR. SOLLER: From CHPA's standpoint, I think

17 the meeting has been very helpful in terms of enhancing

18 awareness, and certainly in terms of a coalition of

19 expertise within the industry and beginning that

20 process. I think that is a positive outcome of

21 scheduling this meeting, and clearly, the definition of

22 the issues and where the various stakeholders are in

1   terms of their staked-out positions, in a sense.

2   My view is that there is -- you know, in the

3   discussions to date here, that there is a pretty good

4   consensus of what the end game here is. And I like the

5   terminology that Tess brought in here of automated

6   identification because it implies the need for

7   flexibility and it implies the need to be aware of

8   technological advances.

9   So therefore, scope and extent become very

10   important issues. I'm not telling you anything you

11   don't already know. But probably here an incremental

12   advance is probably best. It allows a measured

13   business response. It allows the advance of

14   technology. And it most certainly allows the evolving

15   market forces to push all of that along and push it on

16   a lot faster.

17   MS. GREGORY: I would just like to caution

18   about the dangers of inactivity and not doing anything.

19   I think that that's what happened to the blood bank

20   industry, is that, you know, we've been kind of going

21   along and we've identified this and we've identified

22   that, you know.

1   But we haven't really laid out a clear road

2 map, and particularly FDA hasn't laid out clear road

3 map, of we really want you to do this. So

4 consequently, we just sort of keep on, and everybody

5 says to me, well, maybe there will be something better

6 down the road that we should adopt, so let's wait a

7 little while. And consequently, we're still using a

8 barcode from the 1980s, and you can imagine -- you

9 know, if you were using anything else from the 1980s,

10 you can imagine how things have advanced since then.

11   So I think the idea of planning and figuring

12 out what you want to do is very important. But I think

13 having a road map and some sort of target dates is

14 equally important.

15   DR. SOLLER: Could I make one comment here?

16 And this is with sincere, all due respect to the

17 representative from the blood supply industry. And

18 I've benefitted from that.

19   But we heard of a barcode in the 1980s being

20 applied in this comment just now. And I think that's a

21 perspective here. To look on one industry that has

22 done a great job, worked decades to get a process that

1   is pretty close to being in place is a lesson relative

2   to other industries that might be affected by

3   barcoding, and how fast you move, and whether you move

4   to expect a full system or whether you move

5   incrementally, as I mentioned earlier, to allow market

6   forces in this American industry to do some good as

7   well.

8   DR. JOHNSON: I would certainly repeat many of

9   the things I've heard. I think we would all urge

10 action as quickly as possible. But I hope that we've

11 also expressed that there are things that can be done

12 in the nearer term, and things that there need to be

13 more discussion before a reasonable timeline could be

14 agreed upon.

15   So, you know, that's probably as clear as we

16 can be. We could say we would like to have serial

17 number identification on every unit, but that's not

18 very feasible.

19   MS. GIESER: Have any of your members provided

20 you any information about ballpark cost estimates,

21 assuming the simpler case of some unique identifying

22 number being placed on the product?

1   And I know you've mentioned a couple of

2   conditions where the costs become quite high, such as

3   verification or high-speed production and certain

4   package sizes. If you can elaborate in any way on

5   issues of cost, we'd appreciate it.

6   DR. JOHNSON: Are you talking about situations

7   where it would be NDC number only?

8   MS. GIESER: Just to start with the simple

9   case.

10   DR. JOHNSON: I can tell you, because Abbott

11   Laboratories did make a public announcement about this

12   yesterday, so for injectables, we're actively working

13   on implementing barcodes. And we are absorbing those

14   costs. So we're not changing the cost of any of our

15   products.

16   So again, that also feeds into timing. If you

17   do it as a phase-in, it's going to have less of a cost

18   impact. If you require changing all of your labels in

19   a very short period of time, costs can be quite

20   dramatic.

21   But there are always label changes going on.

22   It's how many more are you trying to do in a certain

1   period of time?

2   DR. SOLLER: My experience in doing economic

3   estimates with our members is that it's probably always

4   best to wait till the comment period. Then you know

5   the numbers are there and not provide numbers that may

6   change over time. So undoubtedly, as you're asking

7   this, various groups will be looking at that particular

8   issue.

9   But just a comment, and that is that as a

10 company might move forward and essentially represent

11 the prototype and be willing to absorb costs, I can

12 tell you from looking at all different size companies

13 that that is not necessarily how the production world

14 works, and that ultimately it is transferred out.

15   We don't have specific figures for that, but I

16 think that would be true as well for an institution

17 that might use a repackager, that the end user and the

18 end benefit of that repackaging process is the patient

19 in the institution as it would relate to an OTC, for

20 example.

21   And if that were passed on in that context for

22 whatever the nominal cost would be, spread out over a

1   large purchase, again, it's targeted towards the end

2   user, the end benefitter, of that particular

3   repackaging, as opposed to across the entire gamut of

4   the industry where a large part of our end user would

5   not benefit necessarily from that.

6   MS. CAMMACK: And none of our members have

7   provided cost estimates to us at this time. I do know

8   that there are some members that are preparing written

9   responses to FDA as a result of the Federal Register

10 questions, and you should be getting those within the

11 time period.

12   But I would caution, too, even those that are

13 able to provide cost estimates, when they do it on a

14 product-category-by-product-category basis, what one

15 company may experience or anticipate for costs may be

16 very different from another company putting codes on

17 those very same products.

18   It has to do with the way their particular

19 production line is run, their volume, and where they're

20 located. So there is extreme diversity, not only

21 throughout the industry because of the diversity of the

22 device products, but also because of the company size.

1 So you'll see it from product to product.

2   MS. GREALEY: And I think it's been made clear

3 that you really need to draw the distinction between a

4 more simple versus a more complex data requirement,

5 especially what it could do in terms of reducing the

6 speed of manufacturing and the production line.

7   So that definitely would be a much more

8 significant cost. And again, I'm not even sure that

9 the technology is available to do it in a high-speed

10 way if you were willing to make the investment to do

11 that.

12   MR. BECKERMAN: Just quickly, I was wondering

13 whether any of the industry groups have data on hand

14 about what percentage of products are currently

15 packaged in individual unit dose packages. Or, I

16 guess, a related question: What percentage of

17 products, in a big macro view, are sent to repackagers?

18   And if you don't have that sort of information

19 readily at hand, I'd encourage you to submit it to the

20 docket.

21   MS. GREALEY: The one statistic we can provide

22 is, I think, right now 35 percent of the pharmaceutical

1   products are at the unit dose level.

2   MS. DOTZEL: Okay. I'm afraid we're not going

3   to have time to take questions from the audience for

4   this panel. What I'd ask the panel members to do is if

5   you could, you know, take seats up front, and then at

6   the end of our next session, if we have additional

7   time, we'll give people the opportunity to ask those

8   questions.

9   We're going to take a break now. People who

10   have registered to speak this afternoon, if you could

11   during the break please see Mary Gross. Mary, if you

12   would stand up so people who could see who you are.

13   And she will try to get things organized so that we can

14   move through this afternoon, the second part of this

15   afternoon, quickly so that everyone will have

16   sufficient time to speak.

17   We'll reconvene in ten minutes.

18   (A brief recess was taken.)

19   MS. DOTZEL: I'd like to ask everyone to start

20   taking their seats so we can get started.

21   Okay. We're going to get started. First I'd

22   like to introduce one new member to the FDA panel.

1   Dr. Galson had to leave, and we're delighted to have

2   Paul Seligman here. He's the director in our Office of

3   Pharmacoepidemiology and Statistical Science in the

4   Center for Drugs.

5   This afternoon, for the second part of the

6   afternoon, we are going to hear from speakers who have

7   registered to present their views. The way we're going

8   to try to work this is we are going to ask -- we are

9   going to have people come up to the stage, six at a

10 time. We think it will be easier for you to hear them

11 if they're sitting up here than standing down at the

12 mikes. And so we're going to work it so that we come

13 up to the stage six at a time.

14   I'm going to ask the speakers to use the

15 microphones that are provided at the table. You'll

16 have to switch out there, probably two per microphone.

17 Clearly state your name so that we have that for the

18 record. And I'll let you go down the line, and then

19 we'll bring up the next panel.

20   We'll hold all questions until the end to see

21 that we have time to do it. And if time permits, we'll

22 provide an opportunity, first, for the FDA panel to ask

1   some questions of this afternoon's speakers, and then

2   if we have even more time than we anticipate, we'll be

3   able to turn to the audience.

4   So with that, I'm going to take a seat, and

5   we'll start -- oh, one other thing is, for the

6   speakers, I've turned the timer here so -- the lights

7   aren't on now, but you should be able to see the

8   lights. And it will give you, again, the yellow -- it

9   will turn yellow when you have a minute left so that

10 you can kind of have a warning that time is running

11 close.

12   And again, I'm going to try to keep things

13 moving so that everyone who is registered to speak will

14 have an opportunity to speak.

15   MR. DUNEHEW: Thank you. My name is Allen

16 Dunehew. I am the vice president of pharmacy at

17 AmeriNet GPOs, located in St. Louis. I'd like to thank

18 the FDA for the opportunity to come and participate in

19 this event.

20   It was an interesting discussion this morning

21 and this afternoon. Obviously, varying opinions

22 between the morning and the afternoon, but you can

1 probably understand where those come from based upon

2 the constituencies that each represents.

3   In terms of GPOs, we represent providers who

4 provide direct care. So I think it's important we have

5 large numbers of members, essentially in all practice

6 settings, whether that be physician offices, other non-

7 acute surgery centers, hospitals, whatever.

8   At AmeriNet specifically, we've just gone

9 through a competitive bid process, so I do have some

10 updated information to provide you in terms of the

11 number of products that are available in a barcode

12 fashion.

13   And we do have that data by NDC number,

14 actually, either available today or will be by the end

15 of next year. And I could share that at a later date.

16 We required manufacturers to respond to our bid with an

17 indication of whether or not those products are

18 barcoded or not.

19   To get into some general comments, I think

20 it's important to understand when we start to consider

21 regulation, and actually this afternoon's discussion

22 with the panel probably explains why we're here at this

1   point in terms of regulation, because we don't have a

2   uniform system yet and wide availability of products

3   yet.

4   There were some discussions about what comes

5   first. It's kind of like the chicken or the egg. If

6   the hospitals are not going to invest money into

7   expensive systems if the products aren't there, and

8   they can't afford to do that themselves, the other side

9   of it is true that there has to be products -- there

10 has to be a market for those.

11   And it's interesting that some of our members

12 even indicated that they would be willing to pay a

13 slight upcharge for that availability because they

14 recognize the significant savings and the improvement

15 in patient care that can come as a result of that.

16   Some of the discussion about device versus

17 medication, NDC versus lot number and expiration date,

18 meds used at the bedside versus those that aren't used

19 at the bedside, I would just encourage you to take into

20 consideration we are here primarily because of patient

21 safety.

22   And so when you think about a long-term

1 implementation of barcoding and wait until a complete

2 barcode system is together with lot number and

3 expiration date, I think we have to think about the

4 patient impact of that, and those patients that are

5 going to die in the meantime who could possibly have

6 preventable medication errors just simply by

7 recognition of an NDC number.

8   So when we think about timelines and we start

9 to get out to two years and three years and five years,

10 I think it's pretty obvious and there's very good data

11 about the number of medication errors. Many of those

12 are wrong drug, wrong dose. We know about some that

13 have been highly publicized. Many of those could be

14 prevented with the system. So I'd like to have you

15 take that into consideration.

16   Also, it's true that the availability of

17 barcoding is rapidly changing. So as well as the

18 utilization of systems within hospitals that can

19 recognize that information, the '99 study by ASHP --

20 and I think they said that they're going to have some

21 new information in a couple months -- I suspect that

22 that will be very different.

1   But when you think about those who can scan at

2   the bedside, you have to think about the availability

3   of the medications to scan. One of our members in

4   North Dakota is well along this way, but they put a lot

5   of investment to repackage everything that doesn't come

6   in. Many hospitals can't do that or don't want to do

7   that, so they wait for it to be available.

8   In terms of priority for products, I think

9   it's important, and I personally don't see any

10   distinction between NDC -- or between over-the-counter,

11   rather, and prescription items. I think both of those

12   are important.

13   I think it's important to understand, from a

14   safety process standpoint, the nurse at the bedside

15   needs to work with one system, not a manual system for

16   OTC meds and another system for prescription meds,

17   because you introduce more potential for med errors and

18   it could be worse than what we started with.

19   But when we focus on -- and this primarily

20   also goes to the manufacturers -- think about the types

21   of medications that are used at the bedside. When you

22   look at products to barcode, it's not those with the

1 highest sales dollars nor those that cost the most.

2 It's those that are administered at the bedside where

3 there could be a benefit from barcoding and recognition

4 at the bedside.

5 Unit dose medications, ampules, vials, those

6 kinds of things, certainly not bulk vials that stay in

7 the pharmacy. There may be some barcoding application,

8 but again, if you think about the greatest return on

9 investment, that's going to come from the bedside

10 aspect of that. Topical tubes, medications that are

11 dispensed in eyedroppers, and whatnot.

12 And it's interesting to note, with the RSS

13 technology today, that the barcode scanner -- the

14 barcode symbol is now capable of being put an ampule as

15 small as 2 mls and not compromise the label. So the

16 technology is there. Abbott is one of the leaders, and

17 I've got some other companies that are far along in

18 that stage. But Abbott has put some effort into that

19 as well.

20 MR. ROBERTS: Good afternoon. I'm John

21 Roberts. I'm the director of healthcare for the

22 Uniform Code Council. We're the largest standards body

1   in the world.   I'd like to thank the Food and Drug

2   Administration for this opportunity to talk about

3   patient safety.

4   The proposed rule to mandate barcoding at the

5   unit dose level is essential to improving the quality

6   of patient care.   Medication errors are deadly and

7   costly, and can have a devastating impact on the

8   healthcare industry.

9   Rather than ask the FDA to select a single

10   symbology, such as reduced-space symbology or composite

11   symbology, I instead ask you to endorse the EAN/UCC

12   system for the barcoding of all healthcare products in

13   the United States, and let the marketplace decide what

14   symbol goes on what package, and uses our data

15   structure.   Our data structure already encodes NDC, lot

16   number, expiration date, serial number, and a hundred

17   other different data structures.

18   Barcoding of all healthcare products down to

19   the unit dose has been a goal of the EAN/UCC system.

20   The Uniform Code Council and EAN International

21   developed the reduced space symbology and composite

22   symbology specifically to address this need.

1   Manufacturers, healthcare providers, and

2   leading industry groups have been working with us for

3   the past five years to develop a solution that brings

4   greater automation accuracy and information detail to

5   small healthcare products.

6   What is important to note is the reduced space

7   symbology and composite symbology are just the latest

8   tools of this system. The EAN system is used by nearly

9   a million companies conducting business in 140

10   countries around the world. These standards for

11   product identification and electronic communication

12   allow companies to bring greater accuracy and

13   efficiency to products and the corresponding flow of

14   information.

15   The EAN/UCC system is used by 23 major

16   industries worldwide and provides a global language for

17   companies to identify products, assets, shipping

18   containers, and locations throughout the supply chain.

19   This system has a strong presence in the healthcare

20   industry.

21   Nearly 10 percent of the Uniform Code

22   Council's membership comes from healthcare. That's

1   18,000 of our 260,000 members in North America alone,

2   including manufacturers, retailers, distributors, and

3   healthcare providers.

4   The overwhelming majority of all products

5   purchased by hospitals utilize the EAN/UCC system,

6   whether it is linens, cleaning supplies,

7   medical/surgical products, food, pharmaceutical

8   products, beds, or even flowers, everything a hospital

9   purchases is encoded with our system of barcodes and

10   standard structures.

11   Wherever the healthcare industry has a

12   presence in the hospital and drugstores or grocery

13   stores or any retail store selling over-the-counter

14   products, the EAN system is at work. For nearly

15   30 years, the Uniform Council has provided barcode

16   innovations and has benefitted consumers and industry

17   alike.

18   By selecting RSS and CS, the healthcare

19   industry will be able to utilize their existing

20   investment in the EAN/UCC system because it uses the

21   same data structure as the other symbols. This will

22   cause the least disruption to the healthcare supply

1   chain. It will also allow the industry to implement

2   the FDA mandate faster. Radical system upgrades will

3   not be an issue, so the industry can quickly respond

4   and address the need to reduce medical errors.

5   As a part of the EAN/UCC system, RSS and

6   composite symbology are globally recognized standards.

7   There was a question before about question before about

8   what the Europeans are doing for medication errors.

9   They are very concerned about them because I have

10   e-mails with them back and forth. The Japanese right

11   now, their parliament is looking into this right now

12   and they're in session right now.

13   For medical/surgical items, there is a

14   standard out there. In 1999, the Japanese healthcare

15   industry mandated barcoding on medical/surgical

16   products, to include G-10, lot number, expiration date,

17   and quantity. It took place in 2001. So the Japanese

18   have done this already.

19   Universal guidelines of our system have been

20   established for the placement of symbols, density, and

21   texture, and ANSI grade of the symbol for commercial

22   use. These guidelines could be modified by industry

1 consensus, and have been.

2   RSS and composite can be printed, scanned, and

3 verified by readily available commercial equipment.

4 Two of the leading scanner manufacturers, Symbol and

5 HHP, tell us that there are an estimated two million

6 scanners in the commercial marketplace today that can

7 read RSS or composite.

8   The UCC knows of at least two major

9 pharmaceutical firms that are now labeling or about to

10 label their products with RSS and composite symbology

11 for commercial distribution.

12   It is also important to note that UCC is a

13 neutral, not-for-profit standards organization. The

14 Council does not sell barcodes, software, scanners, or

15 a proprietary solution. There is no vested interest in

16 promoting RSS and composite to the FDA today.

17   Our system is open and voluntary. The patents

18 for RSS and composite, like all our standards, have

19 been placed in the public domain, freely available to

20 any company that wishes to use them. The reason the

21 EAN/UCC system is globally successful is that any

22 company in any industry anywhere in the world can use

1   our barcode and electronic standards and dramatically

2   improve the accuracy, speed, and efficiency of their

3   business.

4   Accuracy is essential to reducing medication

5   errors, and one of the important benefits of RSS and

6   composite is that the healthcare industry will be able

7   to utilize their existing supply chain infrastructures

8   for the use of the system.

9   In closing, we believe the FDA should pick a

10   system that improves patient safety, not just a

11   particular barcode. I am confident the UCC and the

12   EAN/UCC system can provide tools and global strength to

13   help the FDA improve the quality and safety of patient

14   care in the United States. Thank you.

15   MS. DOTZEL: Thank you. Again, I'm going to

16   just urge the speakers to please pay attention to the

17   timer over here.

18   MR. TERWILLIGER: My name is John Terwilliger,

19   also with the Uniform Code Council. I am responsible

20   for directing our various activities across those 23

21   sectors.

22   I would like to thank the Food and Drug

1   Administration for the opportunity to speak this

2   afternoon about patient safety and medication errors.

3   This is an issue that the Uniform Code Council takes

4   very seriously, and we have been working with members

5   of the healthcare industry -- pharmaceutical

6   manufacturers, drugstore retailers, medical/surgical

7   product companies, and healthcare providers -- to

8   important a solution to address this problem. The

9   Uniform Code Council has been at this for about eight

10   years in this whole area of improving patient safety.

11   As John just mentioned, patient safety cannot

12   be fully solved by simply selecting a barcode. The

13   Uniform Code Council strongly believes that the best

14   way to solve the problem of medication errors is to

15   select not a symbology but a system. And the system

16   that provides best performance, global acceptance, and

17   greatest visibility is the EAN/UCC system.

18   This system provides the strength the FDA

19   needs to enable quick response to reducing patient

20   medication errors. For almost 30 years, our barcodes

21   and electronic commerce standards have been used in

22   healthcare for both retail and non-retail applications.

1   Our system of standards is widely established in

2   healthcare and adjacent industries, which will allow

3   your mandate to be quickly and effectively implemented.

4   The system is global and will allow

5   pharmaceutical companies to use a single barcode system

6   to uniquely identify their products anywhere in the

7   world, whether they be retail or non-retail. And a

8   strong consumer focus has always been at the heart of

9   our system. It's always about the end user, when you

10   get down to it.

11   A PriceWaterhouse Coopers study that we had

12   done stated that the UPC alone in the U.S. grocery

13   industry has saved American consumers approximately

14   $17 billion annually, which has enabled greater

15   accuracy, lower food prices, and consumer convenience.

16   This is something that has all happened, and we don't

17   even think much about it. But there's been a lot of

18   money saved.

19   It is because of this track record of

20   performance that the FDA can select the EAN/UCC system

21   with confidence. Reduced space symbology and composite

22   symbology have been specifically developed by the

1   Uniform Code Council and the members of the healthcare

2   industry to improve patient safety by improving

3   identification accuracy at the unit dose level and all

4   other levels of packaging.

5   The EAN/UCC system has had the NDC embedded

6   into it, into the global trade item number, for more

7   than 25 years. The very genesis of this system was to

8   make sure that the NDC number could be incorporated

9   directly.

10   I'd like to make a few points regarding the

11   FDA's proposed rulemaking and how the EAN/UCC system

12   meets the proposed requirements and provides the

13   greatest performance.

14   First, this system is the de facto standard in

15   the over-the-counter retail market, both domestically

16   and in 140 countries around the world. While NDC

17   identification is important, this requirement would be

18   unnecessary in the over-the-counter segment because

19   healthcare manufacturers and drug retailers are already

20   using barcode standards, the global trade item number,

21   or UPC, more simply, to accurately, uniquely, and

22   globally identify OTC products. Mandating the NDC for

1 OTC products would add costs to healthcare and provide

2 no benefit. These products are already uniquely

3 identified per standard. There is no reason to pick

4 another one.

5   Second, the EAN/UCC system's strength and

6 flexibility eliminates the need for a new NDC at every

7 level of packaging. This has been a concern some have

8 mentioned. It's important to know that per the

9 standard, a manufacturer can change the indicator digit

10 which will reflect the particular packaging level,

11 whether it's the unit dose, an intermediate carton, a

12 case, or maybe a whole pallet of product, without

13 changing the NDC number. This will eliminate costly

14 and unnecessary processes that add no value to the

15 quality of patient care.

16   And the third point is that the EAN/UCC system

17 already accommodates secondary information such as lot

18 number and expiration date uniquely. That's very

19 important. We have a way to uniquely identify those.

20 Plus we can include other information such as serial

21 number, if you begin to think about things like devices

22 where the serial number is actually used. We have a

1   way to uniquely identify serial numbers also.

2   Reduced space symbology and composite

3   symbology can incorporate this secondary information to

4   facilitate accurate recalls, enhance inventory

5   controls, and improve drug traceability. It is

6   important to add that secondary information can be

7   carried in the composite symbol over the barcode

8   symbologies of the EAN/UCC system.

9   The UCC is working not only with the

10 healthcare industry, but leaders of many industries, to

11 use this system to improve identification and

12 traceability throughout the global supply chain. In

13 this post-September 11th world, these enhancements will

14 provide immeasurable contributions to public confidence

15 and the safety of our medicines, food, and everyday

16 essentials.

17   With the EAN/UCC system, improved medication

18 accuracy can be achieved. Most importantly, the

19 healthcare industry would be better positioned to

20 deliver an even higher quality of patient care. Thank

21 you.

22   MR. PATTERSON: I am Bert Patterson. I'm a

1 pharmacist, and I'm also the vice president of

2 contracting for Premier.

3   On behalf of the more than 1600 leading not-

4 for-profit hospitals and health systems allied with

5 Premier, I thank the Food and Drug Administration for

6 holding this important meeting on health industry

7 adoption of barcode.

8   For health providers, purchasers, and

9 suppliers nationwide, tapping the potential of new and

10 emergent technology is an integral component of

11 strategic thinking, planning, and execution. Health

12 industry observers herald the potential of technology

13 to promote quality of care improvement and great cost

14 efficiency through a merger of private sector

15 initiatives and public policy.

16   Premier strongly supports the adoption via FDA

17 regulation of an electronically readable uniform health

18 industry data standard incorporating the universal

19 product number, UPN, displayed at every level of drug,

20 device, and biological packaging for the transmission

21 via barcode technology into hospital and vendor

22 information systems. We applaud the FDA's efforts to

1 solicit industry insight and input into the components

2 necessary for successful regulation.

3   UPN implementation and the use of

4 electronically readable identification has vast

5 potential for improving healthcare safety and quality,

6 facilitating clinical product and service, innovation,

7 and enhancing cost efficiency at the supply chain

8 level.

9   The requisite barcode technology exists today.

10 It is widely used, and with documented success in

11 countless other industries, the retail sector perhaps

12 being the most familiar. Premier as a company will

13 require the inclusion of barcodes on all prescription

14 products that are put under contract at Premier as of

15 July 1, '03.

16   Implementation within healthcare has been far

17 less extensive of this technology, particularly at the

18 unit of use level. I must underscore that the failure

19 of our health systems to enhance the technology and the

20 UPN does not imply reticence on the part of our

21 hospitals. Hospitals, in fact, are eager to develop

22 and deploy this kind of technology to improve the

1   quality of care they provide and to achieve economic

2   efficiencies throughout the supply chain.

3   In this regard, I wish to focus on three

4   important areas in which the UPN and electronically

5   readable identification as an essential e-health

6   initiative can achieve sustainable improvements in

7   patient health and safety.

8   The UPN and barcoding have vast potential to

9   facilitate sustained quality improvement and medical

10   error reduction, generate industry-wide cost savings

11   and efficiencies, and enhance knowledge transfer and

12   engender quality improvement through the use of

13   comparative data.

14   While the causes of medical errors and other

15   adverse events are complex, system-based, and deeply

16   rooted, the most immediate and far-reaching remedies

17   lie in the implementation of technology.

18   As numerous interdisciplinary studies have

19   documented, patient safety will be improved, sustained,

20   and reinforced beginning at the supply chain through

21   industry adoption of a standardized system of machine-

22   readable coding on all medication packages and medical

1   devices.

2   Technology advances over the last few decades

3   permit data of ever-increasing complexity to be

4   embedded within barcodes, making possible the coding of

5   increasingly smaller and varied drug and device

6   packaging. The technology is out there. It can be

7   done.

8   In addition to this potential for improving

9   patient safety, UPN implementation can generate

10 significant cost savings and efficiencies across the

11 supply chain. Unlike pharmaceuticals, to which unique

12 National Drug Code numbers are assigned, medical and

13 surgical supplies and devices have no such standardized

14 identification. Clearly, this renders web-enabled

15 linkage of information systems, even for the purposes

16 of comparison, anything but seamless.

17 Federal regulation and support of a

18 standardized system for identification for medical and

19 surgical supplies would greatly facilitate industry

20 compliance and broad-based implementation of these

21 technologies.

22 The 1996 EHCR report predicted that UPN

1 implementation would yield an annual savings of

2 11.6 billion in healthcare supply chain costs. These

3 projected savings are based on the automation of

4 transactions and the integration of a frictionless data

5 stream from point of manufacturer to point of use.

6 EHCR projects that upon standardization adoption of the

7 UPN across the healthcare supply chain, investments in

8 automated transactions would likely bring the highest

9 returns.

10 Finally, UPN implementation holds great

11 promise for knowledge transfer and quality improvement

12 through the analysis and subsequent application of

13 comparative data. Prospective Premier signature

14 healthcare informatics product is the most complete

15 cost-based test-level clinical and financial data

16 warehouse in the country, permitting peer group

17 comparison at the level of resource consumption. In a

18 nutshell, this would enable us to provide an apples-to-

19 apples comparison of hospitals' clinical experience on

20 multiple levels.

21 In conclusion, Premier believes that adoption

22 of an industry standard and requirement of machine-

1   readable identification is a critical e-health

2   initiative with the potential to yield significant

3   progress in patient safety, quality improvement, and

4   cost efficiency.

5   On behalf of Premier, its hospitals and

6   alternate care facilities' patients, I appreciate

7   having this opportunity to attest the potential of

8   technology to reduce the occurrence of medical

9   misadventures, including medication errors, and to

10   positively impact development of e-health and the

11   future of the industry. Thank you.

12   MS. DOTZEL: Thank you.

13   MR. O'BRIEN: Good afternoon, ladies and

14   gentlemen. I'm Terry O'Brien, president and founder of

15   Meds Alert USA, Incorporated.

16   Why not read barcodes in the home? Isn't that

17   where most of the medication errors occur? Would it

18   surprise you to know that barcodes can be read in the

19   home today?

20   As we all know, barcodes are being targeted

21   as a way to reduce medication errors and increase

22   productivity of the healthcare delivery system. We've

1 begun work with the University of Tennessee to that

2 end. We are seeking a strategic partner, and what a

3 better one than the FDA.

4   Meds Alert systems will save lives and save

5 money, 6- to $800 million a year in Medicaid housing

6 costs only if the Meds Alert barcoded system were used

7 in Illinois. This is according to Governor Ryan of

8 Illinois, and the Director of Aging, Margo Schreiber.

9 It would keep people out of nursing homes for mixing up

10 their medications. A recent study has said that we are

11 spending $177 billion a year to correct medication

12 errors.

13   Meds Alert has developed and patented a system

14 to bring the use of barcoded medicine, caregivers,

15 supplies, and equipment into the patient's home or the

16 patient's institutional setting. Meds Alert was

17 granted patents by the U.S. Patent Office within six

18 months because, under patent law, if it would help a

19 cancer or an AIDS patient, they would put it at the top

20 of the list. We received both patents.

21   We also have international patent rights for

22 most of the industrialized world. Meds Alert

1 communications links are wire telephone, cable TV,

2 wireless, and cell phones. Meds Alert raises

3 prosecution compliance by signaling the patient in any

4 language to take their medication.

5   We verify by having them read the -- pass the

6 prescription vial in front of a barcode reader that

7 they have the correct medication. If they don't, we

8 tell them not to take it. If they insist on that, we

9 sound an alarm for noncompliance and send over a

10 caregiver or call 911. We also provide a safe home

11 environment for these people.

12   Good care is compromised by patient

13 noncompliance. Illiterate or those with low health

14 literacy have trouble reading prescription labels and

15 medical forms. Barcodes offer a solution.

16 Noncompliance often leads to emergency room visits or

17 institutionalization. The average cost for a nursing

18 home today is approximately $50,000 a year.

19   Additionally, the Kaiser Foundation on May 2nd

20 just released a study where 4,000 women were studied

21 and found that 21 percent did not even fill their

22 prescription. Meds Alert has a system for that, too.

1   We call it rescribe.

2   According to Kiplinger, the newsletter of

3   6/14, people with chronic diseases are only 20 percent

4   of those insured but make up 80 percent of the

5   healthcare cost. Chronic disease management is the one

6   area sure to reduce healthcare cost.

7   In a Time Magazine article, Dr. Victor

8   Villagra, president of the Disease Management

9   Association and an executive of CIGNA, has 600,000

10   members enrolled in a chronic care program for

11   diabetics. He has seen a cost savings of 14 percent.

12   But he said, and I quote, "This is no longer

13   sufficient. What is, apparently, is having someone

14   tell you to take your medication or else." And I'm

15   wondering if Medicare or Medicaid may be headed in this

16   direction.

17   Meds Alert reminds someone to take their

18   medication and records the event. Who are the

19   chronically ill? There are patients who suffer from

20   heart disease, diabetes, asthma, AIDS, cancer, and as

21   yet uncounted, I believe, the two million plus organ

22   transplant recipients. And I'm wondering if cognitive

1   impairment is counted as that as well.

2   The coming tidal wave of baby boomers will

3   make up 26 percent of the population by 2010, and along

4   with them come the chronic diseases and cognitive

5   impairment. Another serious condition that they bring

6   with them is depression.

7   There are shortages in all areas of

8   healthcare. Caregivers: Daughters primarily provided

9   most home health care, but now most work. Nurses:

10   It's estimated that over 60 percent of them are 40

11   years old, and we need replacements. According to Dean

12   Gorley at the University of Tennessee, there are 10,000

13   pharmacy jobs with no one to fill them.

14   Low wages are another problem. The average

15   paid caregiver, according to a Chicago Tribune article,

16   says that the average caregiver in Illinois makes

17   $18,000 a year. That's not enough to pay for an

18   apartment or for food.

19   The only way to handle the overwhelming

20   problem is automation, barcoded unit dose packaging.

21   Senator Kennedy is on record, and others, that they

22   will introduce litigation this year to reduce

1 healthcare costs by mandating they use automation.

2 Barcodes must be part of that technology automation.

3   The national barcode standard: How close is

4 it? After today, I see that we're working on it and

5 still working on it. But I know that the Uniform Code

6 Council, Health and Human Services, the U.S.

7 Pharmacopeia, and NCCMERP, as well as U.S. drug

8 manufacturers, should want a standard.

9   Meds Alert stands ready with its patented

10 technology to address unit dose packaging. We have a

11 demonstration unit completed, and we welcome discussion

12 with other entities. Our patents allow for migration

13 and expansion. And I thank you for your interest.

14   MS. DOTZEL: Thank you.

15   MR. SIM: Good afternoon. My name is Mike

16 Sim. I'm the chief executive officer of ADVIAS, which

17 is a Virginia-based company specializing in advanced

18 information assurance solutions. We do biometrics in a

19 barcode.

20   You will detect from my accent that I'm not

21 from the U.S. In fact, I've lived most of my life in

22 the U.K., having only been here since September.

1   Questions were asked this morning, what's happening in

2   Europe in healthcare? I think I probably know the

3   answer, having spent 25 to 30 years of my life in

4   healthcare in the U.K.: Very little.

5   Most of the effort, particularly on barcoding,

6   I think was undertaken by myself. I spent two years

7   canvassing to get barcoding used in drug prescriptions

8   for general practice. At the end of that two years,

9   the government was very encouraged, and they said, this

10   has gone almost to the top of the list. This is the

11   second option now. I asked, what's the first option?

12   And they said, no change. And I think there was a very

13   response this morning.

14   Okay. What's a Brit doing here in the U.S.?

15   Basically, I've spent the last six years, having come

16   into the drug industry and a nurse by profession,

17   looking at ways to secure drug delivery. I've been

18   saddened today hearing some of the responses here about

19   barcoding and how far the technology actually goes

20   because I believe it goes a lot further.

21   We have been very forward-thinking in the

22   U.K., and in fact we have a number of systems already

1   running, and running quite well. I won't go over all

2   the problems in the system here in the U.S., or

3   anywhere, really, because those have been covered

4   today, and I think we're all very aware that the wrong

5   patients get the wrong drugs. And even with the most

6   sophisticated pharmacy systems, the wrong drug can get

7   taken off the shelf, and once the label is applied, we

8   all know the consequences.

9   But I think it's also very important to look

10   at -- there have been a number of points today about,

11   you know, do we need to really put additional barcoding

12   on the cover for manufacturer expiry dates. Well, I

13   think we do because the problem is -- the question was

14   asked, how many incidents are there of adverse effects

15   to drugs that have run out of date or drugs which have

16   manufacturing problems? We don't know the answers

17   because we have no way of tracking the drugs.

18   The system today is, if a drug manufacturer

19   finds a problem in their stock, they'll send out a

20   letter to their wholesalers, and the wholesaler will

21   write to the hospitals, and they'll write to doctors,

22   and they'll write to nursing homes, and there's a

1   cascade of letters that go out. But there is no way of

2   tracking those drugs.

3   Nor is there any way of correlating the

4   effects that have occurred with those drugs. And in

5   fact, it will probably need some real clinical evidence

6   to actually show that there is an effect when these

7   drugs are out there.

8   And the U.K. is exactly the same for that.

9   They haven't done anything better, and I don't think

10   the whole of Europe. I hear that the Japanese are

11   moving forward, and I'm not at all surprised.

12   Given that we've got this problem with

13   identifying patients and supplying medication, we also

14   have to look at what's the common link in the supply

15   chain? Well, the common link is the barcode. It is

16   coming through. Manufacturers increasingly now are

17   marking their drugs with barcodes; sadly, not all of

18   them. I think in the U.K. we've got a much higher

19   proportion than you've got.

20   But even if the original pack comes in in a

21   barcode format, perhaps to the barcode format with

22   manufacturer date, expiry date, et cetera, it's then

1 possible, if they have to repackage, to actually copy

2 that through the process.

3   My company has been looking primarily at all

4 the barcodes that are available today, and there are

5 quite a range of barcodes. Now, this morning I heard

6 talk of should we in fact be having a single barcode

7 that refers -- that's a reference?

8   Well, unfortunately, not all care is in

9 hospital. A lot of care may be in hospital. A lot of

10 care may be in outpatients. But a lot of care may be

11 at the roadside. I mean, it may be the paramedics

12 delivering drugs. It may be doctors going out and

13 visiting people in hospitals.

14   And we need to be able to access that

15 information from those drugs wherever we treat them.

16 And I believe the only way to do that is to put a

17 2D barcode on those drugs so that you can actually use

18 equipment. We don't have the luxury of radio

19 connectivity when we're in a patient's home or when

20 we're lying on the roadside.

21   The 2D barcodes that we've primarily worked

22 with is PDF-417, which was developed by Symbol

1 Technologies. The vast majority of you, if you take

2 your driving license out, you'll find it on the back of

3 your license, or military, on the back of your ID.

4 It's a tried and tested product that reads -- sorry.

5 　　　　MS. DOTZEL: Thank you.

6 　　　　MR. WENIGER: My name is Bruce G. Weniger.

7 I'm the assistant chief for vaccine development at the

8 Vaccine Safety and Development Branch of the National

9 Immunization Program at the Centers for Disease Control

10 and Prevention in Atlanta. I thank the Food and Drug

11 Administration for this opportunity to comment on the

12 issue of mandating identifying barcodes on primary

13 pharmaceutical packaging.

14 　　　　For the past several years, I have coordinated

15 the Vaccine Identification Standards Initiative, known

16 as VISI, or V-I-S-I, which is a collaborative effort by

17 a variety of public health agencies and private

18 organizations and groups involved in the practice of

19 immunization, including medical and nursing

20 associations and the vaccine industry itself. Full

21 information about VISI and its recommendations are

22 available at our website, www.cdc.gov/nip/visi.

1   The purpose of VISI is to establish voluntary

2   uniform guidelines for packaging and labeling of

3   vaccines and the recording of their identifying

4   information. The goal is to improve the accuracy and

5   convenience of transferring vaccine identifying

6   information into medical records and immunization

7   registries, and thus to enhance the monitoring of

8   immunization programs and their surveillance for

9   adverse events following vaccination.

10   The National Childhood Vaccine Injury Act of

11   1986 mandates that all persons who administer

12   recommended childhood vaccines must record the vaccine

13   identity and lot number in the medical record.

14   However, evidence from the Vaccine Adverse Events

15   Reporting System, or VAERS, which CDC runs jointly with

16   the FDA, suggests that from 10 to 20 percent of medical

17   records lack these lot numbers.

18   CDC's separate vaccine safety datalink project

19   monitors the vaccination and medical experience of a

20   cohort of 2-1/2 percent of the U.S. population through

21   a network of HMOs. It finds a similarly high frequency

22   of nonexistent lot numbers recorded, and ambiguous

1   vaccine identities, probably as a result of

2   transcription errors and handwriting ambiguity.

3   Among the six major recommendations of VISI,

4   the first is for vaccine vials and prefilled syringes

5   to have RSS, reduce size symbology, barcoding and

6   duplicate or triplicate peel-off stickers containing

7   the National Drug Code, expiration date, and lot

8   number. This information could then be readily

9   captured into the medical records and other forms,

10 either electronically or by old-fashioned peel-off and

11 pasting.

12   We have learned in VISI from our consultations

13 with printing experts in online printing and barcoding

14 experts that the label printing technology has made

15 many advances in recent years that make this

16 recommendation feasible today.

17   This new technology includes labels with

18 multiple layers and peel-off stickers as well as high-

19 resolution, high-speed printers that can print barcodes

20 at the time of vial filling, or online printing in

21 industry parlance. This is important because lot

22 numbers and expiration date are usually assigned on the

1 day of filling and cannot be preprinted on the label

2 stock.

3   In my written statement, which will be in the

4 docket, I understand, are photos illustrating examples

5 of these multiple peel-off stickers and the reduced

6 size barcoding on vaccine vials. I have samples with

7 today. I'm happy to pass them around to the panel and

8 to the audience. Hopefully I'll get them back at the

9 end of the day.

10   The remaining five components which VISI

11 recommends include -- and by the way, if you don't want

12 to wait for the docket, if you'll send me an e-mail at

13 bgw2@cdc.gov, I'll be happy to send you the statement

14 with the photographs.

15   The remaining five components which VISI

16 recommends include full barcoding on the outer

17 cardboard or secondary vaccine packaging of the

18 National Drug Code, the expiration date, and the lot

19 number. Currently, only the NDC is routinely barcoding

20 now, and that's because the National Wholesale

21 Druggists Association insisted on it years ago.

22   Third, a uniform vaccine administration record

1 form to receive the peel-off stickers for non-

2 computerized medical practices.

3   Fourth, a user-friendly National Drug Code

4 vaccine database on the web to assist software

5 developers and others to identify vaccines from their

6 NDC and vice versa, and in the future to convert them

7 to other coding systems like CPT and HL-7.

8   Fifth, a vaccine facts information sidebar on

9 outer cardboard packaging in order to standardize the

10 format and location of key information for safe

11 administration of vaccines, as the FDA has done so

12 wonderfully with its mandated and highly appreciated

13 nutrition facts sidebars on food.

14   And sixth, standardized abbreviations for

15 vaccine types and vaccine manufacturers to save real

16 estate on small peel-off stickers on these vaccine

17 vials.

18   We would particularly urge FDA, in mandating

19 barcodes on unit of use packaging, to specify the use

20 of numbering systems and reduced-size two-dimensional

21 barcoding symbologies promulgated by the EAN/UCC, an

22 international collaboration of nonprofit standards

1 organizations which already set the guidelines for the

2 existing barcodes we now see on pharmaceuticals, foods,

3 and most other products of global commerce. This would

4 avoid the headaches and confusion of a Balkanized

5 system in which manufacturers might use diverse or ad

6 hoc numbering systems or barcode technologies.

7   This could result in much extra work and

8 expense if hospitals and clinics were thus required to

9 set up customized systems to read them all rather than

10 use off-the-shelf hardware and software. Better to use

11 an existing global ID numbering standard already at

12 work in many U.S. hospital receiving docks, warehouses,

13 and pharmacies.

14   Finally, we would suggest that both expiration

15 date and lot number are important data fields for both

16 future bedside monitoring and accurate assurance

17 systems, as well as for existing national drug and

18 vaccine safety surveillance systems. Thank you.

19   MR. KRAWISZ: My name is Bob Krawisz. I'm

20 executive director of the National Patient Safety

21 Foundation. Prior to joining the National Patient

22 Safety Foundation, I was director of business

development for the American Society for Quality and

vice president of the National Safety Council.

I'm here today to speak in favor of barcoding

regulation. The Institute of Medicine reports that

more than 7,000 inpatient deaths per year nationwide

are attributable to medication error. Research shows

that medication errors occur when flaws in the

medication administration process lead to human error.

As we have heard today, a promising strategy

to help avoid these errors is using barcoding to

automate aspects of the process. And I think the time

is now to take that action.

Barcoding has been used effectively for

decades by supermarkets and other businesses, including

healthcare, to reduce errors, improve quality, and

lower costs. Documented improvements in accuracy have

approached the level of sic sigma, and improvements in

productivity range from 30 to 50 percent.

If anyone really cares to look at a variety of

case studies, the Association for Automatic

Identification and Data Capture Technologies on their

website have more than a hundred case histories of

1 using barcodes, and the improvement in accuracy that

2 was obtained, and also the improvement in productivity.

3

4 Barcoding can easily be adapted to medication

5 administration. By printing scanning codes on

6 medication labels and on patient ID bands, machines can

7 readily discriminate one item number from another and

8 identify mismatches.

9 Integrating this technology with a prescriber

10 order entry system and unit dose barcode medication

11 labeling creates an efficient and accurate electronic

12 medication administration system.

13 Kay Willis this morning pointed out that the

14 VHA has taken a leadership role in developing systems

15 with outstanding results in error reduction.

16 I think she pointed out actual improvements of around

17 84 or 85 percent in error reduction.

18 Given a compliance achieved by the Department

19 of Defense and the commitment being made by other major

20 suppliers to support barcoding, now is the time for

21 healthcare organizations to make barcoding part of

22 their overall quality and safety strategy.

1   Kasey Thompson indicated that the American

2   Society of Health System Pharmacists supports marking

3   each container with a standard, compact,

4   multi-dimensional barcode that would contain a reliable

5   drug identifier, lot number, and expiration date that

6   any software program could scan, decode, and report.

7   A single scan could be used to inform users

8   whether they have the right drug and whether the drug

9   had expired. That scan would support lot number and

10   expiration date tracking, which is impractical in many

11   of today's systems because of overhead costs and data

12   capture.

13   The barcode printing and scanning technologies

14   necessary to support this ideal exist today. Lacking

15   such an ideal system, the use of a HBT-compliant

16   barcode containing the NDC code on every container

17   would provide a significant advance.

18   It is recognized that labeling changes create

19   significant regulatory burdens for drug manufacturers,

20   and smaller containers pose label formatting problems

21   that must be overcome. However, some manufacturers

22   have already found solutions to these problems. FDA

1   and/or purchaser mandates are required to move all drug

2   producers to the next level of patient safety.   Thank

3   you.

4   MS. COUSINS: Good afternoon.   My name is Diane

5   Cousins, and I'm here representing the United States

6   Pharmacopeia.

7   USP sets legally enforceable standards for

8   drug products in the United States that include

9   packaging and labeling as well as quality, strength,

10 and purity.   We have been operating a medication error

11 reporting program since 1991, and we spearheaded the

12 formation of the National Coordinating Council for

13 Medication Error Reporting and Prevention.

14   In June of 2001, the National Coordinating

15 Council issued a set of seven recommendations which

16 include a call to action that USP and FDA collaborate

17 with pharmaceutical manufacturers and other appropriate

18 stakeholders to establish and implement uniform barcode

19 standards down to the immediate unit of use package.

20   The Council also urged the expeditious

21 implementation of its recommendations so that

22 healthcare practitioners and organizations could

1 benefit from machine-readable codes present in a

2 standard format on unit of use medication packaging.

3 USP fully supports the Council's recommendations.

4   Insofar as USP is concerned, USP could provide

5 standards for barcoding requirements that would be

6 enforceable under the FD&C Act for official articles.

7 USP awaits the definition of FDA's regulatory authority

8 in order for USP to determine how best to support and

9 compliment these requirements.

10   Because many states recognize our labeling

11 requirements, USP's barcoding requirements could be

12 extended to practice situations such as computerized

13 prescribing and pharmacy dispensing labels.

14   Label readability and product identification

15 have been ongoing issues important in tracking and

16 controlling product quality and information as the

17 pharmaceutical product moves from the manufacturer to

18 the patient.

19   Based on medication errors reported through

20 the USP reporting programs, confusion over the

21 similarity of drug names accounts for approximately

22 15 percent of reports submitted, and as many as

1 33 percent of reports cite labeling and packaging

2 concerns that contribute to medication errors.

3 Barcoded products can help reduce such errors, and have

4 broad impact that spans the multiple phases and

5 settings of healthcare delivery.

6   USP views the barcode requirement as a part of

7 a larger medication error prevention approach, which

8 includes useful and clear names for compendial

9 articles, imprint codes, label simplification, and even

10 standardized prescription ordering.

11   USP is developing new general information

12 chapters on unit of use packaging that may include a

13 discussion of barcodes. USP is considering the

14 advisability of developing other general information

15 chapters that would include guidelines regarding

16 imprint codes and label readability.

17   Therefore, USP supports the December 3 Federal

18 Register proposal, but believes that exemptions should

19 be issued at this time for certain containers,

20 specifically ampules of 5 milliliter size or less,

21 based on the limitations of current technology to

22 accurately and consistently convey information for such

1   package sizes.

2   USP also supports the December 3 Federal

3   Register proposal regarding human drug labeling. USP

4   encourages FDA's expeditious implementation of such a

5   regulation.

6   In closing, USP recommends that a barcode

7   contain, at a minimum, the product NDC number, lot

8   number, and expiration date. This recommendation is

9   contingent on FDA's revision of the current NDC system

10   to provide greater accuracy and consistency to those

11   codes.

12   Barcodes should be standardized in format and

13   information, and should be present on packaging at the

14   point of care, but should not replace human-readable

15   labeling. Thank you.

16   MR. COHEN: I'd like to thank FDA for giving

17   me the opportunity to speak, and also to all of you,

18   thanks for showing up today and supporting barcoding.

19   My name is Michael Cohen. I'm a pharmacist,

20   and I'm president of the Institute for Safe Medication

21   Practices. It's a nonprofit organization located in

22   Huntington Valley, PA. And we work pretty closely with

1 practitioners, healthcare organizations, regulatory

2 authorities, and standards organizations in initiatives

3 to prevent medication errors.

4   Yesterday, for the third time in my career --

5 I guess it's a coincidence that it happened

6 yesterday -- I was called to an organization that had

7 a fatal medication error with potassium chloride

8 concentrate injected directly into a patient instead of

9 another drug.

10   And I had to face one of the individuals who

11 was directly involved in this case, and she was

12 entirely devastated by this incident. Remorseful as

13 she was, there were no words that could describe what

14 an event this was yesterday. And obviously, the family

15 of the patient was devastated, too.

16   And I was asked, you know, for advice on how

17 to prevent errors like this. And there are many ways

18 to do that, of course, notwithstanding the withdrawal

19 of potassium chloride from nursing units. One that

20 struck me, because I was going to be here today, was

21 obviously barcoding of the pharmaceuticals. It was a

22 switch, a swap. She used the wrong ampule. And it

1   could have been prevented, it along with the thousands

2   of others that you've heard about today.

3   Rather than repeat a lot of what you've heard

4   already, because we fully believe in the idea of

5   barcoding unit dose packaging, I'd like to talk about

6   another aspect of this. But I do want to clarify the

7   unit dose package and what we mean by that.

8   I'm talking about a single unit dose, a single

9   dose. This is in contrast to the terminology unit of

10 use, which might be a 30-day supply package in a single

11 package. They're quite different. And what I describe

12 is about unit dose, but all pharmaceutical packaging,

13 including unit of use. But we would like to see the

14 unit dose package with a barcode on it.

15   I wish to focus my attention on the need for

16 barcodes on the unit dose package of medication, and

17 most importantly, the barcoded unit dose packages of

18 medications remain readily available from the

19 manufacturers.

20   The importance of unit dose medication

21 dispensing in the acute care setting has been advocated

22 since the '60s by many organizations. And although

1 this is a proven safe way to provide medications in the

2 acute care setting, especially with the recent use of

3 barcode scanning to match patients' specific doses with

4 the patient and the record, we're experiencing a

5 decrease in the availability of the unit dose package

6 by many manufacturers.

7 And our fear is that many more manufacturers

8 will cease to provide unit dose medications if a

9 barcoding regulation is put in place. We certainly

10 hope that that does not occur. We believe that a

11 regulation is needed, and I don't know how this could

12 even be accomplished. There might even need to be some

13 type of an incentive. But we've got to get the

14 manufacturers to cooperate with the unit dose package

15 itself being barcoded.

16 There are too many hospitals in rural

17 communities that will not be able to afford robotics to

18 do packaging from bulk. And I don't know how else to

19 accomplish this, without the cooperation of the

20 pharmaceutical industry.

21 And let me tell you, the readership of our

22 newsletter is extremely concerned about the lack of

1 availability. We did a survey this past year, and I'd

2 just like to review that very briefly. We have about

3 6,000 hospitals that get our newsletter. And we asked

4 them to respond to a survey. So over 500,000 people

5 read this.

6   Three-quarters of the respondents reported

7 problems with the unit dose packaging of both new and

8 well-established brand oral solid products on the

9 market, including those that had been previously

10 available in unit dose packages.

11   A third reported about six to ten brand

12 products that have not been available in unit dose

13 packaging in the past year. And another quarter

14 reported problems with 11 to 20 brand products. Over

15 6 percent reported problems with more than 40 different

16 brand products. Even more experienced problems with

17 generic oral solid products.

18   Most respondents who repackage medications now

19 estimate a 1 to 10 percent error rate when they do it

20 on their own. So we really need you, manufacturers, to

21 cooperate. It is critical to make this work.

22   It was clear from our survey that despite some

1 initial worry about costs, many hospitals are ready to

2 do their part and move barcode technology forward.

3 About half now consider the availability of unit dose

4 packaging when making decisions about new drugs for the

5 formulary, and two-thirds reported they'd be more

6 likely to select a therapeutically equivalent product

7 if it is available in unit dose packaging.

8 More to the point, 84 percent felt that a

9 slight increase in cost would not deter them from

10 purchasing a specific vendor's product. Only

11 11 percent felt a slight cost increase would be a

12 deterrent.

13 On behalf of its members, you've heard group

14 purchasing organizations like Premier say, let's get

15 this rolling. I hope that it doesn't take what some of

16 the regulations take to formulate and publish in the

17 Federal Register. I too would like to see this, as

18 Premier said, by July next year.

19 ISMP strongly recommends that FDA require

20 barcodes on all medications, to include the NDC number

21 as the standard identifier for prescription

22 medications, the medication's lot number, and the

1   expiration date.

2   However, if necessary, we support a phased-in

3   approach, with the barcoded NDC required as soon as

4   possible and the lot and expiration date required

5   within a time certain. Thank you very much.

6   MS. DOTZEL: Thank you.

7   MS. ENGLEBRIGHT: Good afternoon. My name is

8   Jane Englebright. I'm the vice president for quality

9   at HCA, Incorporated. And I'm speaking to you today as

10   a nurse who has given medications using a barcoded

11   administration system, and who has seen the difference

12   they make in medication errors. And currently, I'm

13   working to roll out barcoding administration to all of

14   the HCA hospitals.

15   I'm testifying today on behalf of both HCA and

16   the Federation of American Hospitals. HCA owns and

17   operates about 200 hospitals and other healthcare

18   facilities in 24 states, England, and Switzerland. And

19   the Federation is a national trade association

20   representing the nation's privately owned and managed

21   community hospitals and health systems from the acute

22   and post-acute spectrum.

1   In February of 2000, HCA made a decision to do

2   its first corporate-wide quality initiative, and the

3   first component of that was improving medication

4   practices. And what we set about doing was trying to

5   improve medication safety, reduce errors, and prevent

6   harm and injury to our patients.

7   We've done that in a comprehensive manner,

8   looking at both operational improvements and the

9   development and employment of two technologies, one of

10   those an electronic physician ordering system, and the

11   second an electronic barcode-assisted medication

12   administration system that's used by nurses and

13   respiratory therapists throughout our hospitals.

14   This is the technology that would greatly

15   benefit from federal standardization of barcoding

16   related to medications. We have 186 hospitals that

17   will have this technology in place by the end of 2005.

18   We have two of them currently doing it, and we'll have

19   two per month coming on board through the rest of this

20   year. We feel a strong sense of urgency. We firmly

21   believe that this technology prevents injury and

22   prevents death.

1   What we have found, to answer a few of the

2   questions from earlier, is that even by moving our

3   inventory in our pharmacies to preferentially buy from

4   manufacturers who provide barcoding at the unit of

5   dose, we still have to repackage about half of what's

6   in our pharmacy. We have learned, with a fairly

7   inexpensive scanning system, how to read UPC, how to

8   read 128, and how to read RSS symbologies.

9   But we are buying packaging equipment and

10   repackaging our medications ourselves for about

11   50 percent of the inventory in each one of the

12   hospitals where we're doing that. We do that

13   understanding that we introduce a potential for a

14   labeling error in the process of doing that, and

15   understanding we're incurring a cost of anywhere from

16   12 to 15 cents per dose, sometimes more for the

17   packaging than it actually is for the pharmaceutical

18   that's contained in there.

19   We believe the process that we've put in place

20   where we have a patient that has their medication

21   profile, their orders from the doctor available

22   electronically, where each dose of medication is then

1 identified with machine-readable code, and where the

2 patient's armband has not only human-readable but

3 barcoded patient identifier on it, are the elements of

4 a safe medication administration system.

5 So the nurse goes to the bedside with a

6 computerized profile of the medication administration,

7 scans each dose of medication to verify that that is

8 what the doctor has ordered for this medication, and

9 the five rights of medication administration have been

10 observed, and then verifies the patient identification

11 by scanning the armband.

12 At the time they file that interaction, then,

13 we have for the first time in our hospitals a

14 comprehensive record of all the chemicals that are in

15 the patient's body, regardless of where in the hospital

16 and who in the hospital has administered that

17 medication, that's available to the physician for

18 clinical decision-making and, maybe even more

19 phenomenally, we have an accurate bill.

20 (Laughter)

21 With that, we would like to encourage the FDA

22 to require the pharmaceutical industry to have

1   standardized machine-readable barcoded information that

2   includes the NDC, the lot number, and the expiration

3   date. We too would welcome a phased-in approach if

4   that is necessary. We believe that the most

5   significant medication errors, the ones that really

6   cause damage to patients, are wrong medication and

7   wrong dose, both of which could be prevented with the

8   NDC number in the barcode. Thank you.

9   MR. ROBINSON: Good afternoon. I am Dr. Skip

10   Robinson, and I have the honor of directing the

11   clinical program for Consorta Catholic Resource

12   Partners. We are the leading healthcare resource

13   management company and group purchasing organization

14   whose shareholders are Catholic-sponsored, faith-based,

15   and nonprofit.

16   I am pleased to have the opportunity to

17   testify to the importance healthcare industry and the

18   people they serve the barcoding of drugs and

19   biologicals. Consorta promotes the use of barcoding

20   technology to create a safer, more efficient, and more

21   effective patient care system.

22   I am here today representing the consensus

recommendation of our over 500 acute care hospitals

representing 70,000 beds, and more than 1800 non-acute

care sites.

As we are all aware, the relationship between

technology advancement in human health, patient care,

and patient safety has greatly improved the health and

mortality of most Americans. However, in some

respects, the healthcare industry trails far behind

many industries in reaping the benefits of new

technologies.

We practitioners are aware that we must find

better ways to verify and review medications before

they are administered to patients. Barcoding of unit

of use medication serves to close the gap in

distribution. Without it, front-end technologies such

as robotic cart fills and drug interaction checks will

never reach full potential. The lack of use of barcode

technology without all those changes will greatly

hinder patient care.

Consorta recognizes that the implementation of

barcodes on the unit of use medication packaging is

only the first vital step in recognizing the promise of

1 barcode technology and making our healthcare system

2 safer.

3   Consorta supports the implementation of

4 requirements of barcoding on all commercially available

5 prescription and nonprescription medications, that

6 barcodes should be included on the labels of all unit

7 of use pharmaceutical products.

8   The NDC code, which is established by the FDA,

9 should be the initial data element included on the

10 barcodes. This should be implemented as quickly as

11 possible. Inclusion of the expiration date and lot

12 number, especially to track recalls and out-of-date

13 products, should be added to the barcode as soon as

14 technically feasible.

15   Consorta supports the eventual inclusion of

16 medical devices for the label recommendation.

17   To conclude, Consorta recognizes that there

18 are some costs associated with this. And we have

19 looked and talked to our hospitals, and they are all

20 willing and ready to aid more money to do this.

21   However, much larger expenditures will be

22 taken out of the system because our institutions will

1 have to adopt these new technologies as they go forward

2 because what we have to do is be able to, at the

3 bedside, check drug/drug, drug/food interactions,

4 laboratory values, allergies, and decisions. They must

5 be done at bedside. Thank you.

6   MR. NEUENSCHWANDER: My name is Mark

7 Neuenschwander. I have been a patient and I am a

8 consultant in the field of pharmacy automation.

9   It was 27 years ago that Wrigley's opened the

10 door by putting a barcode on a pack of chewing gum. It

11 was really a statement of faith because grocery stores

12 and drugstores didn't have scanners. But their faith

13 was not in vain. Within a decade, virtually every item

14 on the shelves of those drugstores and supermarkets had

15 a barcode, and the vast majority of checkout stands

16 were equipped with scanners to read them.

17   Within five years, 1990, virtually every

18 retail item had a barcode, not just Q-Tips at Walgreens

19 and Cheerios at Safeway, but also duct tape at Home

20 Depot and dresses at Nordstrom's. Barcodes on

21 everything, scanners everywhere -- almost.

22   In 1991, the first unit dose medication was

1   barcoded by a manufacturer.   The door was opened.   And

2   ten years later, still two thirds of the medications

3   that make their way from the manufacturer to the

4   hospital bed are without barcodes, and about

5   3 percent -- it's not 1 -- about 3 percent of our

6   hospitals have scanners at the point of medication

7   administration.

8   The reason?   For years, drug manufacturers

9   have argued, why should we apply barcodes if hospitals

10   don't have scanners?   And hospitals have argued back,

11   why should we buy scanners when drugs don't have

12   barcodes?

13   And the whole thing reminds me of a slapstick

14   comedy.   A couple of Keystone Cop cars come to a narrow

15   bridge, not being able to cross, because the drivers

16   are shouting back and forth, "After you."   "No, after

17   you."   And it's been this way for the last ten years.

18   And I am asking you as a concerned citizen and

19   someone who traffics in this world of healthcare, FDA,

20   please help us get this thing across the bridge.

21   There's a wonderful world of safety on the other side.

22   Now, what we all want is labels with

1   medications that contain machine-readable codes -- I'll

2   use the term barcodes -- that can be read at the point

3   of administration. And we've heard all the values

4   about point of administration scanning.

5   I want to reemphasize one other value, and

6   that is documentation at the point of administration,

7   as critical to safety, in my opinion, as verification

8   for when a doctor comes in to evaluate a patient, he or

9   she obvious the patient, looks at the patient

10   administration record, and right now our patient

11   administration records are MARs.

12   Too often we treat them as if M stands for

13   memory. A nurse comes to the end of a shift, all too

14   often, and treats the MAR the way I'm going to treat my

15   expense account when I get at the end of this trip,

16   trying to remember what taxi did I take, was that this

17   day, was the hotel this date. And we end up with an

18   approximate MAR. I want my doctor to have an accurate

19   MAR. Scanning at bedside helps us.

20   Now, which symbologies do we want on these

21   labels? I'll just put it this way: today's

22   symbologies that today's barcode readers can read. And

1 if the Dick Tracy micro-mini radio chips come in our

2 lifetime, we can put them on top. But I'm tired of

3 waiting. I think we all ought to be tired of waiting.

4 Jeez, we've been waiting for Dick Tracy watches since

5 1931.

6   Now, what exactly is it that we want barcoded?

7 Units of use? Unit dose? And all this nomenclature

8 has confused us for years. And as an outsider, I sit

9 and go, what is this? What's that? And I asked some

10 medication safety expert, "What's the difference?" And

11 he says, "Well, my colleague and I disagree, but here's

12 how we define it."

13   An old preacher told a young understudy, he

14 says, "If there's a mist in the pulpit, there's a fog

15 in the pew." Doggone it, there is a fog in the pew

16 when it comes to barcode scanning. There is not a mist

17 in the pulpit, though, if you go back and read the FDA

18 definitions. We're talking about immediate containers.

19 That's the terminology when you talk about labeling.

20   So we're asking you to barcode all immediate

21 containers. What should it include? Obviously, lot

22 number, drug -- I mean, excuse me, drug, strength,

1   manufacturer, lot number, and expiration date.

2   Let me just say this in conclusion, that

3   hospitals have already started across this road. They

4   are going pell-mell into bedside scanning. And they

5   are -- I have been in hospitals where volunteers are

6   slapping barcodes on syringes.

7   There are a reason why we have GMPs. And when

8   we go ahead into barcode scanning, let's not leave

9   those GMPs behind by having hospitals who don't have to

10   comply with those GMPs become packaging houses just so

11   they can scan. Let's help the manufacturers catch up

12   to all these hospitals that are going across the bridge

13   into the future. There's room for two on the bridge.

14   Other than that, I have no opinion.

15   (Laughter)

16   MR. WRAY: Good afternoon. I'm Bruce Wray,

17   the director of marketing at Computype. We're a

18   supplier of barcode labels, label printing systems,

19   scanners, and software. We've served the blood and

20   plasma and general laboratory markets since the mid-

21   1970s.

22   It was my privilege back in October of 1989,

1 at a meeting in the Netherlands, to recommend to the

2 international blood bank community that they switch the

3 standard blood bank symbology from Codabar to Code 128.

4 They adopted that suggestion, and the result was

5 ISBT-128, a formal specification for the identification

6 of human blood and blood products now being adopted

7 throughout Europe but largely being ignored here in the

8 U.S.

9   What did we learn as we developed this new

10 specification? I think we learned several things.

11 First, the statement, "If you build it, they will

12 come," sounds great in the movies, but it isn't true in

13 real life. It would be more accurate to say, "If the

14 law requires it, they will come," or, "If they can't

15 compete without it, they will come."

16   Simply having a well-written and thorough

17 specification, which we did in blood banking, and

18 having that specification available, does not guarantee

19 that it's going to be adopted.

20   Second, we learned that technology is

21 advancing today faster than most formal groups can make

22 decisions about its use.

1   Third, we confirmed what everybody already

2   knows: Barcodes reduce errors. They're fast, they're

3   accurate, and they're easy to use. The case for the

4   use of barcodes or other means of auto-ID is a

5   compelling one.

6   Fourth, and most importantly in my view, we

7   learned the importance of formally agreed-upon data

8   structures as opposed to symbology standards. I think

9   the approach that we used in the development of

10   ISBT-128 was an effective one.

11   It involved the cooperation of all the

12   stakeholders -- blood banks, transfusion services,

13   hospitals, software providers, instrument suppliers,

14   the barcode community, and the FDA. The only thing we

15   lacked was the regulatory impetus for the change to be

16   made.

17   Based on that experience with ISBT-128, we

18   would make the following recommendations to the

19   industry and to the FDA.

20   First, the FDA should require the use of

21   machine-readable symbols on all human drug and biologic

22   products. Eye-readable representation of significant

1   information should always accompany the machine-

2   readable symbols.

3   Two, rather than require a specific barcode

4   symbology or barcode language, the FDA should mandate

5   that an agreed-upon data structure be encoded for

6   machine reading. Were existing standards are

7   available, such as ISBT-128, their use should be

8   required.

9   Third, guidelines should be provided by the

10   FDA to each stakeholder industry group which outline

11   the minimum information content of the symbols and the

12   timeline for implementation.

13   Finally, an auto-ID coordinating council,

14   perhaps made up of some of the wonderful industry and

15   regulatory groups that have been mentioned this

16   afternoon and this morning. That auto-ID coordinating

17   council should be appointed to help resolve

18   implementation issues.

19   It would be made up of volunteers from the

20   disciplines involved in the new requirements, barcode

21   suppliers, and the FDA. It would be charged with

22   ensuring that minimum information requirements are met.

1 It would be charged with maintenance of databases and

2 the assignment of code structures; charged with making

3 sure that the best technology available is used, and

4 that costs to the individual institutions are

5 minimized. Thank you.

6   MR. RITCHIE: My name is Bruce Ritchie. I'm a

7 hematologist, a hemophilia treater, and I represent the

8 Canadian Hemophilia Society and the Association of

9 Hemophilia Clinic Directors in Canada. We also

10 discussed the issue of barcoding in depth with Health

11 Canada, and also with the National Hemophilia

12 Foundation here in the U.S.

13   What I'd like to start out with is to say that

14 machine-readable labeling of pharmaceuticals is clearly

15 something whose time has come. And I think we have

16 heard that today from many, many different people. And

17 I applaud the FDA for moving this process forward with

18 this public meeting. I think it's very important.

19   The FDA must be aware, however, that other

20 regulators are interested in a global standard and are

21 watching to see what the FDA does. I know the

22 Europeans have been waiting to see what the outcome o

1   this and other meetings are before proceeding with

2   standardization there in Europe.

3   Given the success of harmonization in the

4   application for licensure of drugs, I think the FDA

5   should consider harmonization of standardized machine-

6   readable labeling, in particular standardization of the

7   drug identifier, such as the NDC or the GTIN. I know

8   the NDC information can be included in the GTIN

9   standard that's been set by the UCC council.

10   As everyone else has said, I believe labeling

11   of medicines is a safety issue. Everyone involved in

12   the production, distribution, prescription, and use of

13   medicines is responsible, either legally or otherwise,

14   for tracking pharmaceuticals, for monitoring adverse

15   events, and for recall of drugs.

16   So all the players must be able to tell

17   exactly what's in the medicine package and record this

18   information quickly and accurately, and that's where

19   machine-readable labels or barcodes comes in.

20   Machine-readable labels such as barcodes offer

21   dramatically improved speed and accuracy of data input,

22   and will therefore foster the use of database tools

1 which are useful to track drugs, to record and report

2 adverse events as they occur, and to aid in recalls.

3   In Canada, we've developed a national database

4 program called CHARMS, which we use for tracking all

5 blood coagulation products. And when recalls happen,

6 and they happen all too frequently, we in the

7 hemophilia clinics know exactly where the products are.

8 These products are stored in patients' homes in large

9 inventories, which is always a surprise to the

10 governments who are funding these drugs in Canada.

11   So by setting standards of machine-readable

12 labels, the FDA will allow everyone to track these

13 products. And they will encourage drug prescribers,

14 pharmacies, clinics, and users to use this data, and

15 everyone will use this data. I know of three

16 pharmaceutical companies who are setting up global Palm

17 Pilot-based systems for patients to use in maintaining

18 their inventory at home and recording their use of

19 coagulation blood products.

20   Therefore, the simple philosophy that should guide

21 this process is, apply the machine-readable label, such

22 as a barcode, at the source because that's the easiest,

1   cheapest, and most accurate way to do it.   And use a

2   barcode that everyone can use.   This means setting a

3   standard for data format now.

4   And secondly, establishing a harmonized

5   process to set standards for machine-readable systems

6   now and in the future.   As everyone has alluded to, the

7   technology is changing, so we should have a process in

8   place to set standards not only for the present, for

9   today, for barcodes today, but for radio frequency

10   chips for tomorrow.

11   In summary, I think the FDA should think

12   separately about the data format and the way data is

13   transmitted.   The FDA should standardize the data

14   format quickly, and allow manufacturers to add new

15   technologies, meaning new standards for each new

16   technology, to promote a widespread usefulness of this

17   system.

18   The FDA should think carefully about setting a

19   harmonized standard for data format and machine-

20   readable technologies, a widely usable barcode for

21   today, and standardized emerging technologies in the

22   future.   Thank you.

1   MR. STEANE: My name is Edwin Steane, and I'm

2   with ICCBBA. ICCBBA is the group that was alluded to

3   earlier by Kay Gregory as those that maintain and

4   extend the ISBT-128 standard.

5   Bruce has already told you that the initial

6   proposal for the ISBT-128 standard was in 1989. I

7   would point out that it took five years to write that

8   specification. None of this happens as quickly as you

9   think it might, not if you're going to do what we did,

10   which is to adopt three rules: Do it once. Do it

11   right. Do it internationally.

12   We also had another rule that we displayed

13   prominently: Never forget the law of intended

14   consequences. You can do this as quickly as you want,

15   but if you don't put the appropriate thought into it,

16   it's going to fail.

17   As Bruce said, and as Kay said, if you build

18   it, they will not come. The mandate that is needed fro

19   the FDA is the use of machine-readable symbols in

20   therapeutic settings wherever possible. Putting them

21   on products and not requiring that they be used is a

22   waste of time. What's needed is absolute insistence

1 that they be used. The goal should be the elimination

2 of data entry by humans, whether it be through a

3 keyboard or in written notes.

4   I would like to emphasize once again that the

5 FDA should concentrate on data structures. They should

6 not mandate technology. And the Dick Tracy radio

7 frequency tag, by the way, is already available as part

8 of a linear barcode on a blood group label. No one

9 uses it, but it's already available. It's too

10 expensive, of course.

11   So the emphasis should be placed on the data

12 structure, not the means of capturing the data. The

13 industry will look after that very well if you leave it

14 to them.

15   So what should be in the data structures? I

16 would suggest that the FDA can apply a very simple

17 rule. If they require you to capture and record that

18 information, then there should be a standard format in

19 which that information is to be captured. And then

20 putting those into machine-readable symbols becomes

21 relatively simple.

22   Barcoding by itself, although a lot of people

1 in this room don't want to hear me say this because

2 they want to tell you how difficult it is and how

3 complex it is, is trivial. It's the consensus that's

4 needed in order to be able to make the system work that

5 is difficult.

6   Also, the information which is encoded and

7 which appears on a label that an end user is to use

8 should be the information that is of importance to the

9 end user. And you should get everything else off that

10 label because all it does is interfere with what the

11 end user should be concentrating upon.

12   I would suggest to the hospitals, and I've

13 listened to them with care, that if they really want to

14 do something to make this system move, they all need to

15 sit down and talk about a standardized way to identify

16 the patient. And once you do that and the products are

17 barcoded, the errors will go away. Thank you.

18   MR. MAYBERRY: Yes, hi. My name is Peter

19 Mayberry, and I am the executive director for the

20 Healthcare Compliance Packaging Council, which is a

21 not-for-profit trade association founded in 1990 to

22 promote the many benefits of unit dose blister and

1 strip packaging.

2   The HCPC is submitting formal responses to all

3 the questions raised by FDA in the Federal Register

4 notice announcing this meeting, but my purpose today is

5 to underscore one primary point in our responses, and

6 that is that the Institute of Medicine report on which

7 a large part of this effort is based called for

8 recommendations not only for barcoding but for unit

9 dose packaging.

10   And I know you've heard quite a bit of

11 difference between unit of use versus unit dose, but I

12 think Dr. Cohen summed it up very, very well by saying

13 a unit of use can be a container with 30, 60, 90

14 tablets -- it's basically an entire course of

15 regimen -- whereas a unit dose is a single dosage unit.

16   Specifically, on pages 166 through 167 of the

17 1999 report, "To Err Is Human," IOM notes that, "If

18 medications are not packaged in single dosages by the

19 manufacturer, they should be prepared in unit doses by

20 the central pharmacy." The report justifies this

21 recommendation by noting that, "Unit dosing reduces

22 handling as well as the chance of calculation and

1   mixing errors."

2   But the IOM also sounded an ominous alert in

3   this section of the report by pointing out that, "Unit

4   dosing was a major systems change that significantly

5   reduced dosing errors when it was introduced more than

6   20 years ago. Unfortunately, some hospitals have

7   recently returned to bulk dosing as a cost-cutting

8   measure, which means that an increase in dosing errors

9   is bound to occur."

10   Indeed, in the time since the IOM report was

11   first released, the HCPC has heard a growing number of

12   anecdotal reports that pharmaceutical manufacturers are

13   dropping the number of products offered in hospital

14   unit dose or HUD formats. And as recently as May 15th

15   this year, one pharmaceutical manufacturer noted during

16   our national symposium on patient compliance that his

17   company had deleted HUD formats for some 80 percent of

18   their entire drug stock over the past two years.

19   Why are they doing this? According to the

20   pharmaceutical manufacturers, because the hospitals are

21   not purchasing HUDs because they're cheaper to buy them

22   in bulk, just as IOM said.

1   So as FDA considers the user of barcodes as a

2   mandatory requirement, the HCPC recommends that you

3   consider a requirement that the barcode be placed at

4   the unit level. In other words, every single dose of

5   medicine has a barcode on it. The technology is there,

6   and the requirement would be there such that the

7   manufacturer would then have the obligation of

8   providing medications which are intended for dispensing

9   at inpatient settings. Each individual dosage would

10 have a barcode on it.

11   And that would be about the only way that the

12 IOM and the other organizations that have weighed in on

13 this, as well as the practices of many other countries

14 around the world, you would be able to achieve the

15 degree of safety to which you're seeking. That's my

16 primary point for the afternoon.

17   MR. POLINSKY: I'm Steven Polinsky. I am with

18 GenuOne Corporation, and we provide pharmaceutical

19 manufacturers and biological product manufacturers with

20 enhancements that are technology-based against

21 counterfeiting and parallel trade. So we do a lot with

22 barcoding and other marketing.

1   Our solutions include unique machine-readable

2   authentication that can be integrated directly into

3   existing barcodes and other packaging mediums. Also,

4   we enable pharmaceutical manufacturers to print

5   barcodes that are invisible to the human eye. The

6   reason that this is necessary is in the parallel trade

7   and gray market business, gray marketers tend to deface

8   product packaging. So we have to stay one step ahead

9   of these folks with our manufacturers.

10   And it came up today, but it was asked, what

11   other data elements should be considered when putting

12   together some type of barcode standard. And it's very

13   clear to me it should be machine-readable

14   authentication, and the reason being that $12 billion

15   annually of counterfeit medications find their way into

16   hospitals, and especially biological products over the

17   past 18 months have been very hard hit because these

18   drugs are high-priced and have high margins.

19   And the result obviously can be illness and

20   even death. And the bottom line is, even if a

21   counterfeit drug is administered properly, the result

22   can be adverse and be the same. So it's up to the FDA

1   to provide a cost of scale to manufacturers when they

2   build the solution to address both of these issues

3   together.

4   Although the authentication technology is much

5   more sophisticated than barcoding -- barcoding is

6   actually rather simple -- implementation and

7   integration of an authentication mark that's a unique

8   signature that's machine-readable is actually fairly

9   simple. It can be directly put into the ink. It can

10   be into the dye that's actually printed when they print

11   the barcode, the manufacturers, onto a particular box.

12   So it's inherent in what they're doing already.

13   We actually have a lot of clients that are

14   doing this, so they're already providing not only

15   barcoding, but it might be invisible so they can't be

16   human-readable. It can be scanned and it can provide a

17   unique authentication to stay one step and raise the

18   bar on counterfeiters that are out there as well.

19   Scanners can also be retrofitted or calibrated

20   to be able to read these unique marks as they are

21   reading barcoding informatics as well. And this

22   addition to your standard will help mitigate what I

1 believe, and a lot of other people feel, is a major

2 patient safety issue, probably the other big one.

3 That's consumption of counterfeit drugs. Thank you.

4   MR. SCHWARTZ: My name is Robert Schwartz and

5 I'm chairman of the board of the Healthcare

6 Distribution Management Association.

7   HDMA is a national trade association

8 representing pharmaceutical and related healthcare

9 product distribution in the United States. HDMA's

10 distributor members operate over 260 distribution

11 centers nationwide and provide products and services to

12 approximately 120,000 pharmacy settings, including

13 independent, chain, hospital, mail order, mass

14 merchandisers, food stores, long-term care, home health

15 facilities, clinics, and HMOs. HCMA also represents

16 over 220 pharmaceutical manufacturer companies who

17 distribute prescription products from hundreds of

18 facilities.

19   HDMA's mission is to secure the safe and

20 effective distribution of healthcare products across

21 the supply chain from point of manufacture to point of

22 administration.

1   HDMA is supportive of efforts to utilize

2   barcodes at the unit of use level of all drug and

3   biologic products as part of an initiative to reduce

4   medication errors. We appreciate the caution that FDA

5   has exhibited in this process, and welcome the

6   opportunity to work with the agency and other

7   stakeholders to ensure that our efforts enhance patient

8   safety without an undue economic impact to the industry

9   and risk of disruption of the supply of drugs through

10   the healthcare system.

11   HDMA supports barcode labeling for all

12   prescription drugs and vaccines supplied for

13   administration to patients in hospital or institutional

14   settings. We believe this would address the vast

15   majority of critical medication error issues.

16   However, there is no current evidence that

17   this would be so in retail or other treatment settings.

18   To require barcodes on all products in all settings

19   during the initial phase of any forthcoming FDA mandate

20   would greatly add to the costs of barcode labeling

21   implementation and substantially slow the process,

22   causing possible delays in reducing medication errors

1   that are readily avoidable in the near term with

2   current standards and technology.

3   HDMA supports the use of the National Drug

4   Code in any barcode application. The NDC is a standard

5   identifier with a unique, all-numeric system

6   identifying the pharmaceutical manufacturer or

7   distributor, drug product, and package size.

8   It is widely used by manufacturers and

9   distributors throughout the industry, and is already

10   required by FDA regulation. Product and dose

11   information which is included in the NDC number is

12   critical for preventing administration of the wrong

13   medication of strength.

14   HDMA is not aware of any current data

15   demonstrating that the inclusion of secondary

16   information such as lot number and expiration date in a

17   barcode will reduce medical errors. We do not believe

18   that including such information in a barcode at this

19   time will have a noticeable effect on FDA and the

20   industry's goal of medication error reduction.

21   It is our opinion that this information is not

22   critical bedside scanning in order to screen for

1   medication error. Screening for out-of-date or

2   recalled medications should not be performed at the

3   bedside and therefore is not needed in the unit of use

4   barcode.

5   Consequently, HDMA discourages FDA from adding

6   auxiliary information such as lot number and expiration

7   date to the first requirements for barcode usage.

8   Under FDA's current charge to reduce medication errors,

9   especially at the unit of use bedside level, such

10   information is not essential at this time, and

11   inclusion would only add to the costs and complexity of

12   implementation.

13   HDMA does not believe the agency should

14   specify a single barcode symbology and require its use

15   at this time. If FDA limits the healthcare community

16   to a single symbology, it will significantly reduce our

17   ability to comply quickly since more work will need to

18   be done for the industry to adapt.

19   In addition, HDMA finds that two-dimensional

20   symbology is not currently required to meet the goals

21   of error reduction. A linear barcode for the NDC

22   number, supplying product and dosage information, will

1   address the vast majority of medication errors without

2   the need to render entire systems obsolete.

3   The requirement of 2D symbology will add

4   considerable expense and time delays to the supply

5   chain while the industry invests in this still-

6   developing technology. The mandatory use of barcodes

7   will have a significant economic impact on the

8   industry, especially manufacturers and distributors

9   that will be required to invest in packaging

10   technology, equipment components, computer systems for

11   integration, and implementation costs across the supply

12   chain.

13   FDA should not mandate a particular location

14   for the barcode on all products. Variations in size,

15   shape, and packaging will make consistency next to

16   impossible, particularly when viewed in light of the

17   regulated information and presentation already required

18   for medical product labeling.

19   Instead, HDMA recommends that guidelines be

20   offered requiring barcode placement in a way that is

21   fully scannable, especially on small or rounded

22   products. It is far more important to ensure that the

1 barcode is placed in a location where it may be scanned

2 instead of being in a particular location. Thank you.

3   MR. COLLINS: My name is David Collins. I am

4 the president of Data Capture Institute. And our

5 activity centers around the expert development of

6 architectural systems where barcode or auto-ID is a

7 driving influence to the information technology in

8 large enterprises.

9   I'm here to make a recommendation, and the

10 recommendation goes to the heart of controlling the

11 complex, long-life assets used in providing or

12 delivering healthcare. I don't think the position

13 taken earlier today by a panelist saying, forget the

14 medical devices category because you can't justify

15 labeling on a tongue depressor, makes any sense at all.

16

17   There are complex delivery systems used in

18 healthcare. Healthcare is an asset-intensive industry.

19 And they are going without supervision, largely, and

20 primarily because those manufacturers who are

21 delivering these systems don't have a standard format

22 for expressing who the manufacturer is and what that

1   serial number related to the manufacturer is in a

2   format that can be recognized universally, even though

3   one format exists and serves that purpose.

4   The format we recommend is the EAN/UCC global

5   individual asset identifier. It's been available since

6   1995, and it has three principal fields of information.

7   The first field is a message indicator that says, I am

8   an asset and I should be monitored. The second field

9   of information gives the manufacturer identification.

10   The third field of information expresses the serial

11   number assigned by that manufacturer in whatever format

12   the manufacturer desires. It's that simple.

13   Since it's an EAN/UCC standard, it's available

14   for creation of information and support anywhere in the

15   world. And as far as the cost to the label is

16   concerned, this on my fingertip, instead of a 30-foot-

17   long label in a slide, represents such a label. And

18   the cost would be, nominally, five cents.

19   With that label in play, if you will, in the

20   healthcare community, you will find many software

21   providers coming forward with software applications

22   that will allow you to very easily drive a system to

1   monitor assets. That gives you product ownership and

2   stewardship from creation to current use. It gives you

3   in-service history. It gives you repair history,

4   warranty information, reclaimability for recall, and

5   many other features I don't have the time to cover.

6   But it has a precedent being mandated in the

7   federal government today. The FAA adopted this marking

8   systems for suppliers of air traffic control systems in

9   1998, and to date over $2 billion of equipment has been

10   placed on order, and about half of that equipment

11   already delivered, bearing this unique identification

12   which allows the traceability. You might say they're

13   in the healthcare industry as well.

14   With the proper use of this on medical

15   devices, medical devices will always be assigned to the

16   appropriate patient. After patient use, the reusable

17   medical devices will be properly cleaned. Medical

18   devices requiring recalibration will have an audit

19   trail to ensure that this has been done.

20   These assets will be visible through a

21   database screen or a browser, and they will be shown in

22   all their assigned locations. And linking the

1   medication provided to these devices through the

2   methodologies described in most of this conference can

3   be easily accomplished to give one more level of

4   security in healthcare delivery. Thank you.

5   MR. ASHBY: My name is Daniel Ashby. I'm

6   director of pharmacy at Johns Hopkins Hospital, and

7   also associate professor at the School of Pharmacy for

8   the University of Maryland. I'm pleased to be here

9   today to offer comments concerning the needs and value

10   of barcodes, maybe from the perspective of a hospital

11   and a department of pharmacy.

12   I wanted to share two stories with our panel.

13   I'm now part of an organization that finds itself on

14   the front page of the Baltimore Sun and other

15   publications on a pretty regular basis.

16   Sometimes that's a source of pride. Those

17   articles often reflect accomplishments. Sometimes

18   they're accomplishments that reflect what's happening

19   in hospitals all across the country and the efforts

20   healthcare providers everywhere make on behalf of

21   patients in America.

22   Sometimes it's a source of frustration. When

1 we learn that we didn't receive a notice for a recall

2 for a bronchoscope, when we realize that we didn't get

3 the job done, when we realize that patient harm

4 resulted because of that, it creates some real

5 concerns.

6   That event drove us to look at the recall

7 procedure for everything we did in the hospital. From

8 a pharmacy standpoint, I was surprised. There are

9 hundreds of recalls every month. Sometimes it's a

10 capital S versus a small S. That turns into thousands

11 of line items sometimes. It turns into 200 areas that

12 we have to check.

13   Our conclusion was, we did a pretty good job.

14 We thought we usually got the notice. We thought we

15 usually checked all the areas. Well, we usually

16 checked most of the areas. We usually documented that

17 check.

18   Usually isn't good enough. Barcode technology

19 would help. Did we order it? Did we receive it? And

20 where did we ship it to? I don't disagree, we wouldn't

21 do this at the bedside. We would, however, do it at a

22 single unit of use package level.

1   When you distribute the drug to the hospital,

2 you put a hundred doses in a bin. To check them, you

3 have to check them one at a time visually. There is no

4 job more boring in a hospital than checking for expired

5 drugs on the unit. Barcode technology clearly could

6 improve the process and improve the safety of

7 medication use system.

8   A second story I'd share with you: The

9 Department of Pharmacy at Hopkins dispenses 15,000

10 doses or more every day. We've been working hard to

11 decrease the number and percentage of missing doses

12 that occur.

13   We've made progress. We've decreased that

14 percentage from 1.7 to 1.3 percent over the last

15 several months, a 25 percent improvement. That's the

16 good news. However, the bad news is we still have 195

17 missing doses every day. It causes delays,

18 interruptions, and the potential for error.

19   I found it interesting, thinking back last

20 week, that I can send a package to my Peace Corps

21 volunteer son in Honduras, and I can check online to

22 see where that package is. On the other hand, when we

1 get a call from a nurse asking where a dose of a

2 critically needed medication is, we don't know. We'll

3 be happy to send you another one. Do we ever stop to

4 wonder what happened to the other dose and where it

5 went? Clearly, barcode technology can help with this

6 also.

7   To our colleagues in the pharmaceutical

8 industry, we realize this isn't as simple, maybe, as

9 everyone makes it seem. We use the example that we can

10 buy a loaf of bread in the grocery store. If we can do

11 it there, why can't we do it in healthcare? The

12 challenge is more difficult. We want you to wrap each

13 slice individually, and we want you to barcode that

14 slice.

15   The reality, too, though is this isn't new

16 technology. The concept of unit dose is almost as old

17 as mountains. Barcode technology, on the other hand,

18 has been around a long time, too. Group purchasing

19 organizations, ASHP, and associations for years have

20 said, this is the standard. This is the direction we

21 ought to be going to. What you're hearing today

22 shouldn't be a revelation.

1   Two to three years is not acceptable. I'd

2   offer the following four recommendations.

3   In terms of which products should carry

4   barcodes, drug manufacturers should provide all

5   prescription and over-the-counter drugs in barcode

6   packages down to a single unit of dose level.

7   In terms of the information to be provided,

8   clearly the drug identifier, name, strength, and unit

9   needs to be there. But we also need the lot number for

10   recall purposes and the expiration date to prevent the

11   utilization of expired medications.

12   In terms of where the barcode needs to be

13   placed on the package that's going to be used by the

14   patient, if you market a drug in America, you must

15   provide a unit dose or unit of use package.

16   In terms of when, as soon as humanly possible.

17   Two to three years is not acceptable. We haven't been

18   successful with a voluntary effort. We haven't been

19   successful with market forces. Winston Churchill is

20   attributed to have said, "We can always count on

21   Americans to do the right thing, but only after they've

22   exhausted all the other options."

1   (Laughter)

2   A mandate from the FDA is clearly needed at

3   this time.   Thank you.

4   MR. BARENBURG: Good afternoon.   My name is

5   Ron Barenburg, senior vice president of Barcode

6   Technology, Incorporated, or BTI.   Some of you may know

7   us as International Barcode, which is our prior name.

8   BTI specializes in providing barcode software

9   and hardware solutions.   Through our subsidiary S&X, we

10   have provided and serviced Barcode Pro software to over

11   120,000 clients worldwide over the past 13 years.   Our

12   offices are located in New York City and Coral Gables,

13   Florida.

14   Thank you for giving BTI an opportunity to

15   address the FDA and the healthcare community on the

16   need for expert information concerning reduced space

17   symbology barcodes.   This family of barcodes can encode

18   the NDC, or NDC, lot, and expiration date, on various

19   packaging levels of prescribed an/or over-the-counter

20   medications.

21   Ladies and gentlemen, over the past one and a

22   half years, I have traveled well over 100,000 miles to

1 visit many of the pharmaceutical companies here today.

2 Many of you are BTI's clients, and you are the true

3 visionaries.

4   You've not only seen the value of reduced

5 space symbology as an asset in improving patient

6 safety, but as a significant tool for product control

7 and traceability.

8   In August of 2001, under the guidance of the

9 Uniform Code Council, BTI software provided the RSS

10 barcode graphics Abbott Laboratories used to print

11 labels on small vials and ampules. These RSS NDC

12 labels were then scanned at bedside at St. Alexis

13 Hospital in Bismarck, North Dakota. This was one of

14 the first successful pilots of RSS on small unit dose.

15   Since that time, we've come a long way. Two

16 days ago, on July 24th, Abbott Laboratories announced

17 that they pledge to affix unit of use barcodes to all

18 of its hospital injectable pharmaceuticals and IV

19 solutions product lines by early 2003.

20   RSS is currently in use by other companies in

21 the healthcare industry. Its small size, powerful

22 encoding capabilities, and human-readable formats make

1 it ideal to print machine-readable information on unit

2 dose, over-the-counter, and prescribed medications.

3 And it is part of the global UCC/EAN family of

4 barcodes, ensuring worldwide acceptance and use.

5   As its full potential is realized, RSS will

6 also be a solution for encoding information to aid in

7 record tracking and to provide portable databases on

8 medical, surgical, and blood products. RSS barcode can

9 replace the human-readables currently preprinted on

10 labels with a minimum of effort and cost, encoding the

11 NDC number with accompanying human-readables.

12   As for the critical step of placing lot number

13 and expiration dates on products in realtime on the

14 manufacturing line, BTI and its strategic alliance

15 partners, Domino Amjet and Zebra Technologies, have

16 already demonstrated the capability of inkjet and

17 thermal inline printing at line speeds, with laser

18 printing in the near future.

19   Verification prior to webscan: Another BTI

20 strategic alliance partner has off-the-shelf and

21 readily available verifiers to provide ANSI-grade

22 reports on RSS-generated barcodes.

1   Symbol and handheld scanners have both

2 announced substantial sales of RSS-enabled scanners,

3 which can also read all the current symbologies in use

4 by healthcare today. Just as important is the RSS

5 upgrade methods available for existing scanners.

6   This should provide a comfort level that when

7 pharmaceutical companies encode information in RSS to

8 reduce medical errors, end users can have scanners that

9 are available to read that information.

10   We look to the FDA for the following:

11   First, to establish a barcode symbology

12 standard like RSS that has software that is readily

13 available and in use by healthcare today, a barcode

14 that is easily scanned by off-the-shelf, readily

15 available scanners.

16   Second, to provide for an aggressive but

17 realistic time frame for adoption of this barcoding

18 requirement.

19   And third, to establish minimum machine-

20 readable information requirements with implementation

21 of NDC, lot, and expiration date as the fastest

22 timetable.

1   But let us not forget the larger purpose of

2 our work here today. Machine-readable barcoding

3 information and global standardization will save lives.

4 Thank you.

5   MR. SNIPES: I'm Billy Snipes, executive vice

6 president of Returns Online, Incorporated. Our company

7 provides comprehensive recall management services to

8 manufacturers, distributors, and retail entities of

9 pharmaceutical and medical device products.

10   I'm also a pharmacist, and for the last 15

11 years have been involved in the pharmaceutical returns

12 industry and recall industry. We've handled hundreds

13 of thousands of returned pharmaceutical products, and

14 hundreds of thousands of recalled pharmaceutical

15 products. Therefore, I'd like to direct my statement

16 this afternoon regarding the recall end of the spectrum

17 and how I think the safety of the patient could be

18 enhanced there.

19   Returns Online commends and supports the

20 development of a regulation on barcode labeling for

21 human drug products and medical devices for the

22 following reasons:

1   Any human drug product or medical device that

2   will be administered or dispensed to the public should

3   contain a barcode that identifies the drug product

4   through the NDC, the lot number of the batch, and the

5   expiration date of the product. To enforce this

6   stance, let's consider how accuracy and patient safety

7   could be improved in the distribution of the product,

8   the dispensing of the product, and if necessary, the

9   recall of the product.

10   The manufacturer and/or distributor would have

11 the ability to scan the barcode to immediately indicate

12 the lot number and expiration date that it is shipping

13 to an entity, either a retailer or another distributor,

14 and begin the building of a database that would track

15 that drug from either the manufacturer or the

16 distributor to the next step. This database has been

17 mentioned several times today on trackability. How can

18 we track that product all the way?

19   The pharmacist, on the other hand, would be

20 able to scan that bottle or that container and capture

21 that lot number, along with the identification of the

22 product, and further enhance that database. It's now

1   gone from the manufacturer to the distributor to the

2   dispenser.

3   When he dispenses the medication to the

4   public, he would also scan that. It was mentioned

5   earlier that several states had mandated the lot number

6   be put on the label of prescription drugs, and a lot of

7   that, I think, went away because lot numbers are hard

8   to capture manually.

9   They are up to ten characters long, either

10 alpha or numeric. Some of them are stamped on the top

11 of the boxes and are really hard to read. o the

12 barcoding of a lot number onto a container would make

13 it much easier to continue that tracking process.

14   Both the distribution and pharmacy software

15 should have the able to carry a database of previously

16 recalled products. If you had previously recalled lot

17 numbers listed under NDC numbers in a database upon

18 dispensing or distributing, and you scanned that

19 barcode on the container that you're utilizing, if it

20 had been recalled in the past, that would be an

21 automatic flag that that doesn't need to go out. I

22 think the gentleman before me talked about that

1   happening.

2   And a recall is a one-time event for lot

3   number, and specifically. And if it's missed on the

4   shelf, either in the pharmacy or in the distribution

5   center -- because about the only way we've got now is

6   just to go manually look for it. Some of them are

7   missed and some of them are utilized later.

8   It's understood that some of these things

9   could be done by manually entering these lot numbers

10   rather than utilizing the scanner and the barcode

11   technology. However, as I mentioned before, those lot

12   numbers are hard to read.

13   In conclusion, there are a number of far-

14   reaching benefits to expanding current barcode labeling

15   requirements for pharmaceutical and medical devices as

16   it pertains to safety recall management specifically,

17   the accuracy and time efficiencies to monitor and

18   assess the effectiveness of a recall event, and come up

19   with the recall effectiveness.

20   Additionally, automation in the distribution

21   and dispensing level can improve the identification and

22   segregation of recalled product to prevent further

1   distribution, and safeguarding the public against the

2   dangers of receiving outdated and recalled product.

3   Dr. Feigal, I think, mentioned several times

4   the trackability. One of those was that out of a

5   thousand to 1400 medical device recalls last year,

6   sometimes only 5 percent of the recalled product was in

7   hand or gotten back.

8   If we had the ability to track that through

9   the lot number and the databases that we could build in

10 distribution, I think we'd be a lot better off. Thank

11 you.

12   MR. HANCOCK: My name is Ed Hancock. I'm

13 president of American Health Packaging. American

14 Health Packaging is a packaging subsidiary of

15 Amerisource Bergen Corporation, the largest

16 pharmaceutical distributor in the United States.

17   We are a full-service packaging provider,

18 offering pharmaceuticals repackaged under the American

19 Health Packaging label, as well as packaged under

20 contract to manufacturers under their label. We're

21 organized to provide packaging needs to the end users

22 and retail institutional markets, as well as to the

1   manufacturers themselves.

2   Types of packaging that we utilize include

3   bottles, unit dose blisters, and pouches, utilizing the

4   same processes as do the manufacturers themselves. And

5   we also offer pharmaceuticals also packaged in other

6   unit dose formats such as vials, prefilled syringes, et

7   cetera, applying barcodes to those packages.

8   For the sake of time, I'll confine my brief

9   comments to making two points out of the full comments

10   I made to the docket. One is about barcode content,

11   the other about barcoded package availability.

12   Regarding barcode content, product and dose

13   information is critical for preventing administration

14   of the wrong medication or strength. Other information

15   may be useful and may present opportunities for other

16   medication safety activities, but it's not critical to

17   bedside scanning, effectively screening for medication

18   error.

19   The NDC number of a medication is specific to

20   the medication and dose and manufacturer. And since it

21   is available extensively on medication packages today,

22   it makes the most sense to use rather than add any

1   other unique code to the package. The NDC is already

2   the most common barcoded information in pharmaceutical

3   packages, as has been stated.

4   Other information considered, like package

5   type or lot and expiration date, are needed in

6   pharmacies for inventory control purposes, but not add

7   significant benefit to bedside scanning. Screening for

8   out-of-date or recalled medications, as stated before,

9   should not be left to deal with at the bedside.

10   These matters are critically important, but

11   must be dealt with effectively prior to the medications

12   reaching the patient. To regulate barcode content for

13   purposes other than bedside scanning risk adding

14   unnecessary complexity, which can deter implementation.

15

16   The recommendation then is to require the NDC

17   only for the smallest administered dose level. In most

18   cases, that is the unit dose.

19   As a repackager of pharmaceuticals, we've

20   initiated applying barcoded information on all types of

21   packaging for all end use markets. Most major

22   repackagers in the United States have made similar

1   decisions, and apply barcodes to the dose level for

2   unit dose package on pharmaceuticals packaged under

3   their label. A few have demonstrated the capability to

4   apply various symbologies. That creates a source of

5   barcoded packages for every setting where

6   pharmaceuticals are dispensed to patients.

7   The predominant use for barcoded information

8   today is for the inventory control in all settings,

9   institution and retail. But a growing number of

10 hospitals are launching bedside scanning initiatives,

11 as we've heard, and are beginning to use the barcoded

12 information applied to the unit dose packaging for that

13 purpose.

14   In every case where that is happening today,

15 the NDC number, and only the NDC number, is being used

16 as the key information to prevent medication dispensing

17 errors. As we understand it, this is the case at the

18 Veterans Administration facilities reportedly holding

19 the leadership position in these systems.

20   There are many potential uses of barcoded

21 information, and many of them are potentially

22 beneficial to the safety of patients. But all the

1   other uses are facilitated by activities somewhere

2   other than at the bedside, where the most critical need

3   is ensuring the patient is getting the medication

4   prescribed.

5   There are other systems being developed,

6   developed to address the potential for the physician to

7   prescribe the wrong medication, or the prevention of

8   errors in transcribing of prescriptions. All of these

9   preventable systems must happen somewhere before the

10   medication appears at the bedside in the hospital

11   setting.

12   Speaking of availability, even though

13   commercial repackagers today offer many products in

14   unit dose formats for hospitals, many more could be

15   made available with a decision to allow interpretation

16   of the recent U.S. Pharmacopeia and National Formulary

17   guidance as written.

18   The first supplement to USP 25-NF(20),

19   effective April 1st, Packaging Practice: Repackaging of

20   Solid Oral Drug Product in the Unit Dose Container,

21   provides the capability of repackagers to establish a

22   beyond-use state of up to 12 months for oral solid

1 pharmaceuticals repackaged in unit dose formats. Under

2 that guidance, many more products could be made

3 available to the barcode unit dose packages.

4   It is currently interpreted to be only applied

5 to the in-house repackaging dispensers, not to

6 commercial repackagers. We encourage the FDA to

7 consider the extension of that language to commercial

8 repackagers. It would provide many more barcoded

9 packages in hospitals today. Thank you.

10   MR. COUGHLIN: Hello. My name is Mike

11 Coughlin. I'm the president and CEO of ScriptPro.

12 ScriptPro develops and provides dispensing automation

13 and robotics for pharmacies.

14   And unlike much of the discussion we've heard

15 this afternoon, we work in the outpatient

16 community/ambulatory pharmacy environment. And that's

17 a very, very important environment. A very large

18 number of prescriptions, the largest number, are filled

19 there.

20   I wanted to show you how important barcode

21 systems are in what we do. And I submitted a report to

22 the docket here that you have. And I wanted you to be

1   able to see how these systems work, not just tell you

2   how the systems work.

3   So you can go through and you can see how, in

4   these kinds of environments, a drug product is picked

5   up, a manufactured drug product. It is scanned,

6   recognized by its barcode. It is poured into a robotic

7   dispensing cell. That has a barcode on it. The robot

8   manages the process by rechecking the cell. The robot

9   prints a barcode label and puts it on the product. It

10   puts a picture on the product.

11   The patient can take the product home,

12   theoretically scan a barcode, see a picture of the drug

13   they're taking, learn about it, see a picture of the

14   drug on the label. It's all tied together. It's a

15   complete link. That's sort of the heart of how these

16   systems work. I've given you several examples in the

17   reference material.

18   Obviously, these systems are barcode-driven.

19   Barcodes are very important. Unfortunately, sometimes

20   when the patient or the pharmacist scans that barcode

21   with the NDC number on it, our famous NDC number

22   doesn't produce the picture that they were expecting.

1   And this is a serious problem relating to data

2   structure, organization, coordination, standards, et

3   cetera.

4   That's the second half of the pictures in this

5   report, which are not all that pleasant, because what

6   what they're going to show you is that we have drugs

7   out there that have the same barcode, but the drug

8   appears four different ways. Okay?

9   We have drugs out there that are repackaged

10 and relabeled, but the same barcode is there. We have

11 drugs that are dispensed in different packages, and the

12 same barcode may appear on one package and maybe not on

13 another that's an interior pack.

14   It's very easy to find in our drug database

15 systems -- it's very easy to find a barcode that maps

16 back to multiple drug products. The numbering system

17 for drugs has been used in different ways by different

18 manufacturers and repackagers, sadly enough, and this

19 is unfortunate. It's a data structure problem.

20   How did this happen? The National Drug Code

21 neighbor, or NDC, administered by the FDA is a ten-

22 digit number that's made up of three segments, the

manufacturer number, a number that identifies the

product, a number that identifies the package size.

But there is not even agreement, never has been, on the

sizes of these three segments, or consistent use of

these segments. And I've got examples here and

pictures; you can see them.

For example, some manufacturers use the

package size segment to indicate a medical property of

the product. Maybe it works for their inventory

control system, but that's not the way the NDC was

supposed to be used.

There is so much confusion that most computer

databases have expanded the NDC to eleven digits just

to get drug numbers that are not duplicates. They do

this by padding the FDA's NDC with a zero, sometimes at

the front, sometimes at the middle, sometimes just

before the end.

This has introduced even more confusion. You

have before you graphic proof that in our country's

drug numbering system, almost everything that can go

wrong has gone wrong. Let's expand the use of the

barcodes, but let's not do this on the foundation of

1   Murphy's law. Let's fix this foundation before we

2   build it to the next level.

3   Besides dispensing errors, there are other

4   serious problems facing pharmacy today: Critical

5   shortage of pharmacists. Patient wait times are too

6   long. Not enough time for patient counseling. The

7   good news is that barcode-driven systems, properly

8   designed, can help us solve all these problems at once.

9   I have a series of recommendations that are in

10 the report: that we fix the numbering system itself;

11 that we have a clear definition of what barcodes are on

12 the drugs; and above all, get the lot numbers and

13 expiration dates in these barcodes; and have a

14 different barcode and a different drug number for a

15 different drug, even if it only looks different,

16 because if you can't verify it by looking at it, what

17 good does the number do for you? Thank you very much.

18   MS. LONGE: My name is Karen Longe. My

19 company is Karen Longe & Associates. And we specialize

20 in assisting the healthcare industry in the use of

21 automatic identification and data capture, including

22 barcode. And I would like to thank the FDA and all of

1   you here for the opportunity to make comments on this

2   issue that's really impacted the entire industry, right

3   down from the manufacturer to the patients.

4   However, today I'm here as chair of the

5   healthcare committee for AIM. AIM is the association

6   of automatic identification data capture technologies.

7   AIM is committed to standards development, education,

8   and market promotion. It has a membership of over 900

9   companies, global companies, that provide the equipment

10   and systems that capture, track, and transfer

11   information about people, places, and things.

12   I would first of all like to compliment the

13   healthcare industry for developing and approving

14   standards. There are standards out there for making

15   products. Those standards include the health industry

16   barcode supplier labeling standard, the EAN/UCC system,

17   and the ISBT-128 system we've heard about, as well as

18   the health industry barcode provider application

19   standard for identifying other things that we're

20   probably not talking about today except for patients,

21   that Ed Steane mentioned.

22   The most important part of developing the

1 standards was to identify the nature of the information

2 that should be encoded in a barcode, and how the

3 various elements of the information should be

4 identified and presented. The really important part of

5 that work, and perhaps really the one I noticed, was a

6 realization that before considering a particular

7 barcode symbology or any other kind of radio -- excuse

8 me -- any kind of machine-readable technology, such as

9 RFID or contact memory, the business problem had to be

10 clearly defined.

11   This is because all of these technologies that

12 can be used to automatically identify products and

13 collect information, they're only tools. These

14 technology tools continue to change and, fortunately,

15 in most cases, improve.

16   I also would like to insert a word of caution.

17 Some of the things we've been hearing today about the

18 method to encode the information, to limit it to

19 barcode only or, I think, even more dangerous is just

20 specify only one barcode symbology.

21   Doing something like this would be like a

22 specification back in the mid-'60s that said that all

1   information had to be collected on punch cards; or

2   maybe the music industry said, okay, the only thing

3   we're ever going to do is allow 33-1/3 LPs. Where

4   would we be today? While I agree that standards are a

5   must, please, don't be limited by the technical

6   advancements. Don't limit it so the advancements --

7   you can't take advantage of them.

8   Another point that should be made: The

9   industry is looking at barcoding as a tool to improve

10 patient safety, but there are many other business

11 benefits of barcoding that should not be overlooked.

12 Manufacturers, distributors, healthcare facilities,

13 will benefit from the ability to identify and track any

14 type of product -- the drugs, medical devices, blood --

15 from the point of manufacturing through distribution to

16 receiving, use by healthcare facility, and then of

17 course the reordering process, and everything starts

18 again.

19   The technology that works best on a pallet of

20 products is not necessarily the one that works best at

21 the unit dose or unit issued level: Again, my concern

22 over legislating a technology rather than identifying

1   the elements of information and how they are presented.

2   That's why healthcare developed standards that -- and

3   they developed the standards that improved the

4   standards that are based on data structures.

5   These standards allow for the use of several

6   different AIM-approved and tested symbologies. Data

7   structures provide a description and the order of the

8   data to be encoded in a symbology or an RFI tag or a

9   contact memory button.

10   Be assured, though, that current technology

11   out there -- the barcode printers and scanners we've

12   been talking about today -- they do produce and read

13   the full range of publicly available barcode

14   symbologies identified by the healthcare standards.

15   Mandating the use of appropriate machine-

16   readable technology, using a health industry-developed

17   and approved standard, will help to improve patient

18   safety and improve efficiencies in the healthcare

19   chain; will allow the industry to take advantage of

20   advancements in technology to meet their own business

21   needs. However, mandating a particular technology or a

22   particular barcode symbology will limit the industry's

1 ability to reach its goals.

2 The members of AIM are ready to assist the FDA

3 and the healthcare industry as it moves forward to gain

4 the benefits offered by automatic identification and

5 data capture. Thank you.

6 MS. SENSMEIER: My name is Joyce Sensmeier.

7 I'm here on behalf of the Healthcare Information and

8 Management Systems Society. It is a nonprofit

9 association focused on advancing the best use of

10 information and management systems for the betterment

11 of human health.

12 We are based in Chicago. We have more than

13 13,000 individual members who work in healthcare

14 organizations throughout the world. The individual

15 members include healthcare professionals and hospitals,

16 healthcare systems, clinical practice groups,

17 healthcare information technology supply organizations,

18 consulting firms, and government settings, in

19 professional levels ranging from senior staff to CIOs.

20 HIMSS also serves over 80 corporate members, which

21 include suppliers and consultants in the health

22 information and management systems industry.

1   HIMSS strongly supports industry cooperation

2 in achieving viable point of care unit of use barcoding

3 to reduce medical errors and improve productivity.

4 HIMSS members represent all aspects of the supply chain

5 impacted by unit of use barcode technology.

6   HIMSS is working to accelerate the adoption of

7 barcoding at the point of care through several

8 initiatives: publication of a white paper on

9 barcoding; formation of a supply chain special interest

10 group; formation of a barcoding task force; development

11 of a flow chart describing the effect of barcoding

12 technology on the continuum of care, which has been

13 submitted to the docket as Exhibit A to my statement;

14 joining the National Alliance for Health Information

15 Technology as a founding member, and you heard from

16 that group this morning.

17   We have plans for developing a barcoding

18 handbook to assist providers with the implementation of

19 this technology. And we have also developed a HIMSS

20 position statement on point of care unit of use

21 barcoding, which follows.

22   With the goal of moving towards a fully

electronic health record system, the Healthcare

Information and Management System Society advocates the

comprehensive use of standards-based barcoding

technology in the healthcare environment.

And the Society recognizes that significant

benefits of this technology can be brought forward in

multiple areas, including: patient registration and

admission; patient safety; clinical care delivery;

patient tracking; product supply logistics; materiel

management coordination; and patient accounting and

billing, which was mentioned this afternoon, not

altogether unimportant to some people.

At our annual conference in January, we polled

attendees to see what was the use of barcoding

technology in their organizations. Nearly 77 percent

of the 619 respondents of the survey reported that

their organization was using barcoding technology in

some way.

The two areas which reported the most

prevalent use were laboratory, 45 percent of the

respondents, and the supply chain/materiels management

at 40 percent. However, only 15 percent of our

1   respondents indicated that their organization used

2   barcode technology for medication administration at the

3   point of care.

4   It is our recommendation that barcoding be

5   applied immediately to the medication administration

6   process. Use of this technology, along with embedded

7   decision support, which includes alerts and reminders,

8   will go far to enhance patient safety at the point of

9   care and provide the nurse with support in documenting

10 and administering timely, accurate, and effective

11 medication therapy.

12   On a personal note, I would like to share a

13 brief experience that I witnessed back in the 1980s

14 working as an R.N. in a 350-bed community hospital. I

15 worked with a nurse named Claire who was exactly the

16 kind of nurse that I would want taking care of me if I

17 was a patient. She was bright, thorough, efficient.

18 She questioned the physician's orders when they needed

19 to be questioned. And she provided excellent care.

20   One day Claire made a grievous medication

21 error. Her patient was a 300-pound truck driver who

22 was recovering from arm surgery and various multiple

1   trauma injuries.   He was on a blood thinner to prevent

2   blood clots.

3   The dose was ordered for 9:00 a.m. daily, but

4   we had a protocol in place that you should check the

5   blood level of the drug prior to giving the medication.

6   On this particular day, in a rush, Claire gave the

7   blood thinner without checking the blood level. It so

8   happened that the patient's blood level was high, and

9   the patient bled internally into his surgical incision.

10   The blood was trapped. He developed

11   compartmental syndrome, and eventually became disabled

12   from his truck driving job. Needless to say, Claire

13   was devastated by this situation, but each of us knew

14   that it could have happened to any of us.

15   Today's environment in healthcare is even more

16   challenging than in the 1980s: fewer resources, a

17   nursing shortage, and patients in the hospital are

18   sicker. Barcode technology provides a check and

19   balance at the point of care. With embedded decision

20   support, it could prevent errors like this. Please

21   take action quickly so that this technology can be used

22   to help us provide optimal patient care.

1   MR. ROSADO: Good afternoon. My name is Edith

2   Rosado and I'm vice president of pharmacy affairs at

3   the National Association of Chain Drug Stores.

4   NACDS is pleased to provide comments on the

5   development of a regulation on barcode labeling for

6   human drug products. NACDS supports the use of

7   barcoding for all prescription products, vaccines, and

8   over-the-counter medicines to help improve the quality

9   of pharmacy care provided to patients, as well as to

10   create efficiencies in the provision of prescription

11   services.

12   NACDS membership includes more than 200 chain

13   pharmacies that operate 33,000 community retail

14   pharmacies. Chain pharmacy is the single largest

15   segment of pharmacy practice, employing approximately

16   100,000 pharmacists.

17   Chain community pharmacy fills about

18   70 percent of the three billion prescriptions provided

19   to patients each year. It is predicted that community

20   pharmacy will fill roughly four billion prescriptions

21   by the year 2004. And again, 70 percent of these

22   prescriptions will be filled by chain community

1 pharmacy.

2   This fact, coupled with the continuing

3 shortage of pharmacists, including 6500 vacancies alone

4 just in chain community pharmacy, will require that

5 community pharmacy seek technological solutions to keep

6 up with the increasing demand of prescriptions in an

7 efficient and a safe manner.

8   NACDS supports the use of barcode through that

9 supports not only the NDC but also the lot number and

10 expiration date of the product down to the unit of

11 dispensing package. With all three pieces of

12 information present, the product can then be tracked

13 throughout the supply chain system from point of

14 distribution from the manufacturer to the end user

15 patient.

16   From a patient safety perspective, this is

17 important information to have, especially during a drug

18 recall. Additionally, having this information as part

19 of the barcode makes tracking of inventory a much

20 easier task. This becomes a useful tool when dealing

21 with return goods and inventory management.

22   NACDS supports the use of barcodes as a way

1 to compliment the various programs that community

2 pharmacies already have in place to enhance patient

3 quality. Many automated dispensing systems that are in

4 use today accomplish this goal.

5   A recent chain market survey shows that

6 45 percent of the chains surveyed use barcode scanning

7 for data entry and prescription verification. One in

8 particular allows the pharmacist to scan the barcode on

9 the label of the completed prescription.

10   This allows viewing of the image of the

11 correct product. The pharmacist can then compare and

12 doublecheck the image against what is in the pharmacy

13 container before it is ultimately dispensed to the

14 patient.

15   Pilot tests are also being conducted to

16 investigate the use of barcoding for proper drug

17 selection. The barcode is scanned at the point of data

18 entry so that the NDC, drug name, and strength

19 automatically populates the necessary fields on the

20 computer screen.

21   This eliminates the need to choose one drug

22 from an entire alphabetic list. When all fields are

1 then populated, other dispensing functions, such as

2 drug utilization review and billing, may also be

3 conducted since many of these functions depend on the

4 NDC number and specific product information.

5 Enhancing barcoding will substantially improve

6 the current FDA recall system. In recall of product

7 withdrawal situations, all affected product must be

8 identified or removed from the marketplace. Especially

9 during Class 1 recalls, the pharmacist must contact

10 every person who has received the drug to warn them of

11 possible adverse reactions as well as to communicate

12 the need for product withdrawal.

13 If lot numbers were utilized as part of the

14 barcode and recorded as part of the patient's

15 prescription record, identification of the affected

16 patient population then becomes easy. The pharmacist

17 only needs to contact those patients that have actually

18 received the affected product, eliminating unnecessary

19 alarm to other patients since they would have to

20 contact all patients that received the prescription in

21 question.

22 Additionally, the pharmacist would also be

1   able to pull all this unwanted stock expeditiously from

2   their pharmacy shelves, their warehouse, and

3   distribution center.

4   Using barcodes could also facilitate other

5   patient quality initiatives. New technologies exist

6   that allow the physician to send the prescription

7   electronically to the pharmacy provider of the

8   patient's choice. Electronic prescribing helps to

9   eliminate ambiguous abbreviations and specifies all

10 elements needed for a complete order -- the drug name,

11 dosage, directions, and the route of administration --

12 thereby reducing the chance for medication-related

13 errors.

14   Barcoding technology also increases

15 efficiency. In fact, barcoding technology could be

16 considered as an alternative to keyboard data entry.

17 Barcode scanners are faster than the human eye and much

18 more accurate, and tests have shown that barcode

19 information has an accuracy rate of one error in ten

20 million characters, versus keyboard data entry error of

21 one in 100.

22   Efficiencies and technology in community

1   retail pharmacy have allowed the pharmacist to spend

2   less time on the administrative tasks of filling the

3   prescription and more time interacting and counseling

4   the patients about their prescriptions. A recent study

5   conducted by Arthur Andersen found that pharmacists

6   still perform many of the tasks filling prescriptions

7   that do not really need to be performed by pharmacists.

8   That is, they're spending over two-thirds of

9   their time on tasks such as computer data entry,

10   counting and packaging medications, resolving

11   prescription insurance program disputes, and other

12   clerical activities. These non-clinical tasks consume

13   pharmacists' valuable time that could be better devoted

14   to patient care activities.

15   MS. DOTZEL: Thanks very much. We need to

16   move on.

17   MR. RACK: I'm Robert Rack, president of Rack

18   Design Group and BarcodeAmerica.com.

19   I have the benefit of 27 years of experience

20   implementing automatic identification solutions in

21   barcode, and maybe uniquely, six years experience

22   working for a major pharmaceutical firm, so I

1   understand the issues from both sides, and providing

2   end user solutions with our present company.

3   Let's not decide that a 1 percent

4   implementation level dictates the technology chosen.

5   The issues are safety, compatibility, reliability,

6   affordability, product security. Commonality of data

7   structures are a must. The ability to fit the data on

8   the drug or medical device is paramount. Potential

9   lethality of the drug or device should be considered in

10   determining whether NDC number encoding alone is

11   sufficient. Increased danger mandates NDC number, lot

12   number, and expiry date and coding.

13   Product cost and potential for counterfeiting

14   may mandate the use of a supplemental four-character

15   alphanumeric serial number to identify it to the

16   individual unit level. A four-character number would

17   allow 1.6 million possibilities in a lot.

18   On some medical devices, this is necessary,

19   too, to have traceability because you cannot tell by

20   looking at the device if certain operational steps have

21   been done on it, like heat treating and things of that

22   nature.

1   In terms of choosing a symbology, we could use

2   code 128. We could use RSS. We could use data matrix.

3   All those codes should be acceptable. NASA did their

4   evaluation of product marketing, and they chose data

5   matrix codes, as have several other industries.

6   A point I'd like to make is that handheld

7   readers capable of reading all existing codes can be

8   purchased today for less than $500. By this time next

9   year, due to the development of CMOS imagers on a chip,

10   cost of handheld readers will drop to $200 to $250 to

11   read every symbology that exists.

12   At this time, the capability for printing data

13   matrix codes at the fastest line speeds exists. RSS

14   can be printed at lower line speeds. High-speed

15   thermal transfer or inkjet printing that can meet

16   quality requirements in vision systems that can read

17   and determine anti-print grades now exists for matrix

18   codes, and can be run at line speeds up to 2,000 labels

19   per minute.

20   We first installed data matrix systems on

21   pharmaceutical lines in 1994. It's proven technology.

22   Virtually any system installed in the pharmaceutical

1   industry over the last three years for human-readable

2   date and lot inspection is also data matrix capable.

3   The pharmaceutical manufacturer merely has to enable

4   this capability.

5   High-speed machine vision systems capable of

6   reading RSS will start becoming available within 60

7   days. These will initially command a premium price.

8   Installed costs for such systems will start at about

9    $16,000. Costs for installed medium-speed data matrix

10   systems start at about $8,000. It is anticipated that

11   at some future date, the same systems will read all the

12   RSS variants at similar costs.

13   Data matrix could be installed and made

14   operational sooner by pharmaceutical companies than RSS

15   codes. It also uses the least label real estate,

16   allowing it to fit where other symbologies will not.

17   Some existing online laser systems will be

18   capable of being upgraded to RSS if the laser

19   manufacturers have the incentive to do so. It's not

20   assured.

21   What makes sense? Perhaps we should phase in

22   lower lethality drugs first using only NDC or UCC/EAN

1   standards over the next 18 months. For higher

2   lethality drugs or drugs with higher counterfeit

3   potential, the NDC, lot and expiry, and possibly

4   sequential numbers should be phased in over a 36-month

5   period, giving time to acquire the printing systems,

6   the online printing systems, that are needed and need

7   to be implemented.

8   This way, the pharmaceutical manufacturers

9   will have time to invest, install, and validate the

10   online printing and inspection systems. People have to

11   remember that time is required to do validation and do

12   the equipment purchase. But the first phase will not

13   require these upgrades to online printing capability

14   since this data can be printed offline.

15   Manufacturers could also possibly chose the

16   50 percent of their products that will fall into the

17   first phase. My concern otherwise is that

18   implementation will be stalled and deadlines extended,

19   much as what happened with component verification

20   during the '90s.

21   Lastly, consider that image-based readers are

22   capable of reading all symbologies and performing image

1 capture.

2   A point to consider: Perhaps if the

3 physicians' signatures were captured, you would be more

4 careful and lower the opportunity for transcription

5 errors. Thank you.

6   MR. CREQUE: Good afternoon. I'm Stewart

7 Creque, vice president of business development of

8 findtheDOT. Thank you for allowing me to make this

9 presentation to you today regarding the barcode

10 labeling regulation. We put specific answers to your

11 questions into our docket submission. I just want to

12 use this presentation to set the background for that.

13   findtheDOT has developed a unique new

14 technology for creating links between physical objects

15 and digital data that relates to those objects. This

16 alternative to barcode solves problems that have so far

17 prevented wider acceptance of machine-readable codes

18 for patient safety.

19   Automated identification of unit dose packages

20 at the patient bedside is a key element and the last

21 line of defense in preventing medication errors in the

22 clinical setting. While bedside verification systems

1   using traditional barcodes have shown good success when

2   used as designed in reducing medication errors, these

3   systems have not achieved widespread acceptance. This

4   is due to three factors.

5   The cost of packaging unit dose medications to

6   fit barcodes: Traditional barcodes are large and

7   therefore require large packages, which waste material

8   and add cost. And they also rely on inline printing at

9   production speeds for variable data elements.

10   Cost of bedside verification systems: Barcode

11   scanners are relatively expensive and are incorporated

12   into very costly systems requiring major IT

13   investments. If the current barcodes are replaced by

14   RSS, CS, or data matrix-type codes, acquisition costs

15   of scanning hardware will rise substantially.

16   And third, reluctance of bedside staff to

17   utilize unwieldy barcode scanning hardware and

18   software: Barcode scanners are inconvenient at the

19   bedside and the software driving them is generally

20   complex, slowing down the bedside nurse.

21   findtheDOT's MedDot technology improves both

22   sides of this tradeoff by offering, first, a code

1 physically small enough, just 5 millimeters in

2 diameter, to fit onto existing packaging and on other

3 small spaces such as infant wristbands or custom

4 dispensing labels.

5 Second, low-cost readers within the reach of

6 hospital capital budgets such that every bedside nurse

7 can have a personal reader at an affordable total cost

8 to the hospital, including a low-cost, low-power RF

9 link in each device.

10 And third, a linking mechanism whereby any

11 MedDot can link to a related data set that can contain

12 any types and quantity of data, both static and

13 dynamic. Dr. Combes of the AHA alluded to that in his

14 remarks this morning.

15 This removes barriers both to rapid deployment

16 of machine-readable codes on unit of use packages and

17 rapid implementation of bedside scanning systems at

18 hospitals. And further, because MedDots support a code

19 space of ten billion billion unique values, each and

20 every unit dose medication, biologic product, and

21 medical device can have a unique serialized identifier

22 link to a specific design, manufacturing, and use data,

1 including who ordered it, who dispensed it, and who

2 administered it.

3   Instead of being forced to print at production

4 line speeds, the manufacturer can preprint MedDots onto

5 packaging material along with the nonvariable data,

6 inspect them offline, and then pre-load the database

7 with product information.

8   At the time of packaging, the manufacturer

9 updates the MedDot database with the lot number and

10 expiration date. And when the product is sold, the

11 data can be transferred to a local system at the

12 purchasing hospital. Of course, MedDots can also be

13 generated in the hospital pharmacy for nonstandard or

14 custom preparations.

15   On the nursing floor, a nurse uses the MedDot

16 reader to identify the patients assigned to her that

17 shift and each of her patients' medication orders, the

18 MAR, are wirelessly transmitted to her MedDot reader.

19 As she prepares to administer medication, she reads

20 MedDots on the patient wristband and on the unit dose

21 package and receives positive confirmation that the

22 five rights of medication safety are satisfied, and, of

1   course, a negative confirmation if they are not.

2   MedDots all have the same small size and

3   distinctive appearance for ease of visual

4   identification. And the MedDot reading device can

5   prompt for further data such as route of

6   administration, and also can accept charting notes from

7   a pocket menu card.

8   The system thus supports automated charting as

9   well as reporting of near-misses or of errors. It also

10   supports inventory control and other administrative

11   functions in the hospital.

12   So this simple technology can be incorporated

13   easily with existing hospital IT systems. And,

14   moreover, findtheDOT will gladly license the MedDot

15   reading capability to vendors of barcode-based systems,

16   and we will also license pharmaceutical manufacturers

17   and barcode equipment manufacturers at very low cost in

18   order to make MedDots a healthcare standard. Since

19   bedside scanning is still rare, there is really no

20   significant installed base of barcode scanners to be

21   displaced in that application.

22   The MedDot is an innovative technology that

1   breaks the existing logjam in acceptance of machine-

2   readable codes for bedside verification, and as such,

3   it offers an immediate increase in patient safety.

4   Thank you.

5   MR. EDZENGA: Good afternoon to all that's

6   left. I'm Larry Edzenga. I represent the vaccines

7   biological products manufacturers' position on unit

8   dose barcoding of VISI. Just a reminder:

9   VISI is the Vaccine Identification Standard

10 Initiative. I'm representing the vaccine manufacturer

11 member companies from Aventis Pasteur, Careon,

12 GlaxoSmithKline, Merck, and Wyeth, working in

13 conjunction with the Centers for Disease Control and

14 Prevention, Bruce Weniger.

15   In our effort to reduce medical errors, the

16 VISI members companies align with the PhRMA statement

17 that was presented earlier as a co-contributor to the

18 development of that document.

19   VISI members are -- I want to say, though,

20 unlike PhRMA, our challenge with the vaccine and

21 vaccine labeling is a little different than PhRMA's.

22 It's included in PhRMA's recommendation. However, we

1   have some particular issues around size when it comes

2   to prefilled syringes and vials.

3   So VISI member companies have researching

4   barcode technologies in the market, done extensive work

5   in this area, in our effort to meet very small

6   available space to print on vaccine labels and at high

7   running speeds in production, and in particular,

8   variable data, and in particular, for the base label,

9   let alone any detachable labels.

10 VISI member companies conclude that reduced

11 size symbology is required, and specifically two-

12 dimensional data matrix is selected code to barcode

13 vaccine labels, again because of size. VISI member

14 companies feel it has met the objective for vaccine

15 standard barcode identification for users from

16 affordable scanning technology now available, and can

17 read multiple barcode symbologies.

18 VISI member companies, however, are also

19 concerned the public health organizations and physician

20 offices will use barcodes provided on labels by the

21 industry. As we heard earlier, vaccines make up about

22 1 percent of hospital dispensing at bedside.

1   Government agencies will need to educate and

2   poll the medical community for the appropriate use to

3   meet the objectives barcodes are intended. VISI member

4   companies want to continue to work with the CDC, the

5   agency, and healthcare stakeholders of this process in

6   an effort to reduce medical errors. Thank you.

7   MR. RIDDICK: I'm John Riddick, director of

8   quality assurance and regulatory affairs for Novation.

9   I requested to speak on behalf of Novation today

10   because of my expertise in the regulatory and quality

11   arena, especially as it relates to medical labeling and

12   barcode applications. I also come to you today as a

13   representative of America's leading hospitals.

14   Novation is the supply company of two large

15   not-for-profit hospital alliances, VHA and UHC. These

16   alliances represent more than 2,300 community-based

17   medical centers ranging in size from 20-bed rural

18   facilities to multi-thousand-bed teaching institutions.

19   We estimate that the two alliances account for about 35

20   percent of the occupied beds in the country. In 2001,

21   the purchases of Novation contracts amounted to almost

22   $18 billion.

1   Through our work with Novation, we regularly

2   come into contact with physicians, nurses, pharmacists,

3   and other clinicians practicing in our hospitals of all

4   sizes. Continually, they tell us that one of the top

5   priorities for their hospitals, in keeping with their

6   focus on patient safety and cost-effectiveness, is

7   barcoding on as many medical products as possible.

8   Selection of safer products and prevention of label

9   mixups and medication errors are key goals in Novation

10   institutions.

11   As part of our member-driven philosophy,

12   Novation has launched a comprehensive safety

13   initiative, including, among other programs, the

14   requirement for machine-readable barcodes at unit of

15   use. A daunting challenge for all of us is the

16   application of barcodes on the very small product

17   containers, especially pharmaceutical vials, in light

18   of the FDA's current requirements around human

19   readability.

20   There are certainly smaller barcodes in the

21   newer emerging technologies. We all want to make sure

22   that the systems in each of our individual hospitals

1   are capable of reading any applied barcoding.

2   As requested in the Federal Register, our

3   guidance to FDA is as follows:

4   Number one, mandate the use of machine-

5   readable barcodes at the unit of use level on all

6   dosage forms of commercially available pharmaceutical

7   products, blood products, and vaccines.

8   Number two, initially demand that all the

9   information contained in the NDC number is included in

10   that barcode.

11   Number three, with respect to time frames,

12   urge the suppliers to make this change as soon as

13   economically feasibly possible. Novation has set the

14   deadline for our suppliers for 2004.

15   Number four, consider the inclusion of lot

16   numbers and expiration dating in the barcode when the

17   technology is more widely available and when the end

18   users are more universally prepared to read and scan

19   these new technologies within their institutions.

20   Certainly, inclusion of the lot number and expiration

21   date will benefit end users when tracking expired

22   products or recalled products, and Novation supports

1   the inclusion and asks FDA to address it as soon as

2   technically feasible.

3   Number five, eventually consider the use of

4   barcodes on medical devices. As relates to safety

5   issues, prevention of medication errors, et cetera,

6   many medical devices would not even need a barcode.

7   Priority should be given to those devices that have

8   potential to adversely affect patient safety.

9   As stated by many here today, the critical

10   need to move immediately in the area of pharmaceuticals

11   should not be diluted by consideration of barcodes on

12   medical devices at this time.

13   Number six, evaluate and promote new and

14   emerging technologies that we've heard about so many

15   times today, such as radio frequency, dot matrix, 2D,

16   or NSS, as they become more readily available and

17   easily embraced by end users.

18   In the near term, however, FDA should not

19   require the application of barcodes beyond the scope of

20   one-dimensional symbologies currently available and

21   widely used.

22   And number seven, consider relaxing the rules

1   surrounding human-readability requirements, especially

2   in the extremely small containers. If there were more

3   space available on the small labels, the supplier and

4   the end user would benefit from the added flexibility.

5   Although suppliers are in agreement that

6   barcoding would be a positive step, all the ones that

7   we talked to tell us the same thing we hear from our

8   customers: Yes, it's something they would like to do.

9   We feel that a standardized, comprehensive FDA

10   directive will further move those suppliers to accept

11   this important enhancement, as well as lead consistency

12   to the process.

13   Most imply, these improvements could only

14   promote patient safety and help to reduce medication

15   errors while streamlining cost savings and

16   efficiencies. Thank you.

17   MR. HENNUM: Hi. I'd like to thank the FDA

18   for the opportunity to address the proposed regulation

19   on barcode labeling. My name is Vaughan Hennum. I'm

20   CIO for Portex, Inc., which is part of Smiths Medical.

21   And I am representing an actual mid-sized device

22   manufacturer selling to the acute care marketplace who

1 might be affected by a barcode regulation.

2   I'm going to focus principally on the economic

3 impact questions, and try to share a few insights about

4 what we think something like that might cost us. I

5 think our situation might be illustrative for other

6 suppliers. I think, honestly, just from a casual

7 survey of other device manufacturers, device

8 manufacturers have a way to go in this arena.

9   First off, will barcode printing costs cause

10 changes in labeling for the Smiths medical companies,

11 it absolutely will. We have implemented barcode item

12 number case label printing, but we are not far along on

13 unit of use.

14   There's no question that our regulatory

15 function demands validation and verification of any

16 barcode labels. That's a real cost. We do item

17 numbers on the case label, but lot number and expiry

18 dates, we've got a ways to go.

19   We do agree there are equipment solutions out

20 there. But one of the things that really concerns us

21 the most is the rate of technology acceptance and the

22 time for this regulation to become effective.

1   I'm going to read you a quote. "HIDA and the

2 industry need medical/surgical manufacturers to

3 identify with industry standard product barcodes by" --

4 the target date for very small unit of use was July

5 1997. That was published in July 1995.

6   That hasn't happened, and the real question

7 is, why not? And I think it comes down to, who is the

8 owner or stakeholder of barcodes? If you examine other

9 industries that have been very successful with

10 barcoding throughout the supply chain, whether it's

11 retail or automotive, ultimately you had a large end

12 user who said, if you want to sell to me, you must

13 barcode.

14   In Japan, which has been alluded to, we are

15 actually seeing now some large university hospitals

16 saying, even if the price is higher, we will buy only

17 barcoded products at the unit of use level with lot

18 number and with expiry date.

19   So the challenge, it seems to me, in the

20 health industry, which does not have large consolidated

21 hospitals to drive all elements of the supply chain to

22 barcode, is how do we get there? The solution that

1   we're talking about is an FDA regulation, which has

2   compliance through the entire supply chain.

3   The reality is, for a medical device

4   manufacturer, barcoding at the unit of use level, item,

5   lot number, expiry, will cost a significant amount of

6   money and time to implement and to validate, with very

7   little internal gain, especially considering, as

8   someone pointed out today, the multiple language

9   labels. And I'm going to actually go through what

10 we've estimated our costs to be for our company.

11   So I guess I would say if we are to move

12 forward with this expenditure to avoid the failures of

13 past voluntary compliance initiatives, the regulation

14 must cover the entire supply chain with standard, well-

15 accepted barcode symbologies to avoid the high cost of

16 new technology, with existing data structures such as

17 UCC-128.

18   Just as a for instance, we have about 3,000

19 SKUs. We've estimated that to do the entire piece of

20 capital investment as well as labor, IT, et cetera,

21 would look like about $650,000. And that doesn't

22 include the ongoing cost of additional labels.

1   For Smiths Medical, across all of the

2   manufacturing companies, we've estimated that the cost

3   would be three-quarters of a percent to 1 percent of

4   our revenues to effect this regulation.

5   So in conclusion, then, my point in making

6   this presentation is, we think the benefits appear to

7   be clear for barcoding. It seems like it's a very good

8   public policy to improve patient safety. But if the

9   FDA regulates barcoding, it must drive that compliance

10   throughout the entire medical device supply chain by

11   regulation for patients to obtain the benefits of our

12   expenditures.

13   I am not limited just to suppliers. We think

14   that it would take us about two years to actually

15   implement this regulation. We could do item number

16   first. Lot number and expiry date are more

17   challenging.

18   Thank you very much for the opportunity to

19   make this presentation.

20   MR. PEOPLES: Okay. MACs people, are we still

21   all awake? I am a pharmacist. I have both community

22   and hospital experience. I currently am the president

1   of Rxscan.   Rxscan has for several years developed

2   national drug barcode scanning equipment and processes

3   used to reduce medication dispensing and administration

4   errors.

5   Currently, our equipment is used to verify the

6   accurate dispensing of over 100 million prescriptions

7   per year.   Hopefully, this practical experience means I

8   know something about what I'm going to talk about

9   today.

10   Since we started out today with a video, as a

11   windup, why don't we just do a quick 30-second live

12   case demonstration.   Here's the patient.   This patient

13   is represented by a barcode.   I scan that barcode.   The

14   scanner now knows the information on what drug this

15   patient is supposed to receive.

16   I now take my medication container.   It could

17   be this enteric coated aspirin that is barcoded here.

18   I scan this product.   It yells and screams at me and

19   gives me a red light, saying I just about gave the

20   wrong medication to this patient.   That's two seconds,

21   and it takes two seconds of training.   This is what

22   we've spent the whole day talking about.   This is what

1   all of this effort is for.

2   Which medical products should carry a barcode?

3   It is my belief that all healthcare products should

4   carry a barcode. This includes medical supplies,

5   prescription medical products, and over-the-counter

6   should carry a national drug barcode.

7   It is necessary, obviously, to increase

8   utilization of automation to decrease medication errors

9   and distribution costs. We include nonprescription

10   products because OTC medications are also administered

11   to patients in healthcare facilities and sometimes

12   dispensed by prescriptions in community pharmacies, OTC

13   medicines, like aspirin, laxatives.

14   Everyone in here would like to make sure they

15   receive the right laxative. Right? Or how about not

16   get a laxative when they're not supposed to? Vitamins

17   are often prescribed. Prescribing them is often done,

18   so is there a complete medical record of what the

19   patient is taking and the specific directions for that

20   patient on that patient's container?

21   Currently many over-the-counter products, such

22   as diabetic supplies and insulin, have both an NDC

1 number and a UPC, a universal product code number. And

2 usually it is the universal product code number that is

3 barcoded. Why did we have two identification numbers

4 for the same product? Also, for billing purposes in

5 healthcare, the UPC number is not normally recognized.

6 It's only the NDC number.

7 　　　　　Almost weekly, we hear of serious drug

8 interactions occurring when mixing certain vitamins,

9 herbals, and other OTC products with prescription

10 medications. Having one ID number, the NDC number,

11 barcoded on all over-the-counter products will expedite

12 the identification of these potentially dangerous

13 interactions using software drug interaction programs.

14 　　　　　What information should be contained in the

15 barcode? The minimum information is the National Drug

16 Code. That is the common ID that we need to eliminate

17 dispensing or administration errors. Lot number and

18 expiration date? We've all got lots of great reasons

19 why we need those, but it is not the most important

20 element to eliminate these errors.

21 　　　　　Our statistics show -- obviously, we can

22 capture data in this scanner. Our statistics show that

1 over 5 percent of the first medication that is pulled

2 from a shelf to supply to a patient is not the

3 medication that is in the patient's medical record.

4 Okay?

5   Should we adopt a specific barcode symbology?

6 Pros and cons:

7   Pro: Adopting one barcode symbology would

8 speed up the process of adopting universal medication

9 barcode scanning by, A, allowing the hardware

10 manufacturers producing everything from barcode readers

11 to barcode printers to focus on making the best

12 equipment at the best prices possible for a single

13 symbology, not many different symbologies; B, the

14 medication manufacturers and packagers to focus on

15 getting barcoding accomplished as rapidly as possible.

16   Con: It restricts future adoption of improved

17 barcode symbology technology.

18   We believe a compromise is to have just a

19 general requirement that whatever we come out with has

20 a linear component that will work with today's

21 equipment. That way, today's stuff will continue to

22 work for as long as it needs to work anywhere in the

1   distribution process.

2   What packages -- or where should it be on the

3   package? We'd like to see it down to the package that

4   gets closest to the patient. So here's a sample.

5   There's a barcode on the outer package. It comes in

6   boxes of three. This is an inner package. This is

7   what the average person is going to get. It also has a

8   barcode.

9   But what happens when we get into a situation

10 where what the patient actually is going to get is the

11 individual dose right here? Okay. That also is

12 barcoded. That's what we mean when we say, get down to

13 the dose that gets closest to the patient.

14   What products already contain barcodes?

15   MS. DOTZEL: I just need to ask you to wrap

16 up.

17   MR. PEOPLES: Sure. Basically, in community

18 pharmacy, which is where most of our stuff is used,

19 most community pharmacy products are bulk. They're

20 already packaged. The stuff that we're really talking

21 about today is hospital and nursing home-based. Thank

22 you very much.

1   MS. DOTZEL: Okay. Well, we heard a lot of

2 great information this afternoon. I apologize to

3 people for having to cut you short or not give you

4 sufficient time to probably give us all the information

5 that you wanted to give us.

6   Obviously, we, you know, heard a lot of really

7 good things. We think that everybody out there has a

8 lot of valuable information. And we encourage you to

9 give us the additional information you have. Submit

10 your comments to the docket.

11   As I said earlier today, the docket closes on

12 August 9th. The docket number is on the notice, the

13 meeting notice you have. And if you don't have a copy

14 of that, you can probably still get a copy out of the

15 registration desk or from our website.

16   I think we heard a lot of support today for

17 this initiative. We heard a lot of people say that --

18 you know, express their feeling that we needed to

19 approach this thoughtfully. We needed to think about,

20 you know, the scope of this. We needed to think about

21 implementing and how and how far we would go with our

22 implementation.

1   And I think another big thing that we heard

2 today was flexibility and the need to adopt something

3 that does -- that allows for, you know, technological

4 innovation as we move forward.

5   We appreciate everybody's input today. And

6 again, I urge people to continue to give us that

7 information over the course of the next few weeks while

8 the docket is open. And with that, I will close the

9 meeting. And thank you very much for your

10 participation today.

11   (Whereupon, at 4:50 p.m., the public hearing

12 was concluded.)

13   * * * * *